

Financial Conflicts of Interest in Research

PURPOSE

The purposes of this Financial Conflicts of Interest Policy are:

- To ensure that design, conduct and reporting of research activities conducted or supported by BCW are free from bias resulting from financial conflicts of interest and are performed in accordance with the highest ethical and scientific standards.
- To ensure the proper stewardship of BCW’s charitable assets and protect the tax-exempt status of BCW.
- To establish a consistent written process for the disclosure of actual and potential Conflicts of Interest and the identification, reporting, management, reduction, or elimination of Conflicts of Interest.
- To ensure compliance with applicable laws and regulations.

POLICY SUMMARY

The Policy describes the process for the disclosure, identification, reporting, management, reduction, and/or elimination of financial interests and potential or actual conflicts of interest by BCW personnel and others who propose, conduct or support research at BCW.

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POLICY

1. DEFINITIONS

For the purposes of this Policy, capitalized terms shall have the meanings set forth below.

Financial Interests, Significant Financial Interests*, Financial Conflicts of Interest*

**Note: Significant Financial Interests and Financial Conflicts of Interest must be disclosed in accordance with Section 3.*

“Financial Interest” means any of the following interests held by a Research Staff Member or his/her Family Member(s):¹

1. With regard to any publicly traded entity, a 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;
2. With regard to any non-publicly traded entity, a 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 Research Staff Member or his/her Family Member(s) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. Reimbursed or sponsored travel related to Institutional Responsibilities, except for travel that is reimbursed or sponsored by (a) a Federal, state, or local government agency, (b) an Institution of higher education as defined at 20 U.S.C. 1001(a), (c) an academic teaching hospital, (d) a medical center, or (e) a research institute that is affiliated with an Institution of higher education.²

The term “Financial Interest” does not include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by BCW to the Research Staff Member if the Research Staff Member is currently employed or otherwise appointed by BCW, including intellectual property rights assigned to BCW and agreements to share in royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Research Staff Member does not directly control the investment decisions made in these vehicles;
3. Income from seminars, lectures, or teaching engagements sponsored by (1) a Federal, state, or local government agency, (2) an Institution of higher education as defined at 20 U.S.C. 1001(a), (3) an academic teaching hospital, (4) a medical center, or (5) a research institute that is affiliated with an institution of higher education; or
4. Income from service on advisory committees or review panels for (1) a Federal, state, or local government agency, (2) an Institution of higher education as defined at 20 U.S.C. 1001(a), (3) an academic teaching hospital, (4) a medical center, or (5) a research institute that is affiliated with an institution of higher education.

“Significant Financial Interest” means a Financial Interest that reasonably appears to be related to:

1. the Research Staff Member’s Institutional Responsibilities; or
2. the Research Staff Member’s research activities; or
3. any person or entity, other than BCW, that develops, markets or sells health care or biotechnology products or services, including but not limited to, pharmaceutical companies, device manufacturers, suppliers, health care service or provider organizations, information technology companies, and biotechnology and bioengineering companies.

Examples of Significant Financial Interests include, but are not limited to:

- A Research Staff Member’s spouse has \$10,000 of stock in a pharmaceutical company.
- A Research Staff Member receives a \$6,000 honoraria from a medical device company.
- A Research Staff Member receives royalties related to a licensed biological product.
- A Research Staff Member’s spouse receives \$7,000 to provide consultation services to a biotechnology company.

“Financial Conflict of Interest” or **“FCOI”** means a Significant Financial Interest that the BCW Director of Research Administration or the RCOI Committee reasonably determines could directly and significantly affect the design, conduct, or reporting of BCW research.³

“Designated Institutional Official” means the institutional official who is designated by BCW to review Significant Financial Interests and ensure compliance with federal and state regulations.⁴ The BCW Designated Institutional Official is the BCW Executive Vice President of Research (or his/her designee).

“Director” means the BCW Director of Research Administration.

“Disclosure Statement” means a BCW-approved disclosure statement. See Exhibit A.

“EVP of Research” means the BCW Executive Vice President of Research (or his/her designee). The Director of Research Administration and the BCW RCOI Committee will assist the EVP of Research.

“Family Member” means a Research Staff Member’s spouse/domestic partner or dependent children.⁵

“Institutional Responsibilities” means a Research Staff Member’s professional responsibilities on behalf of BCW, including research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.⁶

“PHS Awarding Component” means the organizational unit of the PHS that funds the research.⁷

“Public Health Service” or **“PHS”** means the Public Health Service 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 National Institutes of Health (NIH).

“Research Conflict of Interest Committee” or **“RCOI Committee”** means the EVP of Research or the BCW committee designated by the EVP of Research to review Significant Financial Interests held by BCW Research Staff Members and their Family Members, chaired by the EVP of Research. All of the activities delegated to the RCOI Committee in this Policy may be performed by the EVP of Research.

“Research Staff Member” means an individual, regardless of title or position, who is responsible for the design, conduct, or reporting of BCW research, including a fellow and graduate student, project director, principal investigator, collaborator, consultant or other staff member who is responsible for the design, conduct, or reporting of research.⁸ The RCOI Committee will identify and maintain a list of Research Staff Members.

2. APPLICABILITY

2.1 BCW Research Staff Members

This Financial Conflicts of Interest in Research Policy shall apply to all BCW personnel, including BCW Research Staff Members. The Research Conflict of Interest Committee (RCOI Committee) shall identify and maintain a list of BCW Research Staff Members.

2.2 Subrecipients

If BCW carries out PHS-funded research through a Subrecipient (e.g., subcontractors or consortium members), BCW will take reasonable steps to ensure that Subrecipient Research Staff Members comply with federal conflict of interest regulations by incorporating as part of a written agreement with the Subrecipient terms that establish whether BCW or Subrecipient’s financial conflicts of interest policy will apply to Subrecipient’s Research Staff Members.⁹

- (a). Compliance with BCW Policy. If a Subrecipient’s Research Staff Members will comply with this Policy, the written agreement with the Subrecipient will specify time period(s) within which

Subrecipient's Research Staff Members will submit a Disclosure Statement to BCW. Such time period(s) shall be sufficient to enable BCW to comply timely with its review, management, and reporting obligations under federal regulations.¹⁰

- (b). Compliance with Subrecipient Policy. If a Subrecipient's Research Staff Members will comply with the Subrecipient's financial conflicts of interest policy, the written agreement with the Subrecipient will: (i) include Subrecipient's certification that its policy complies with federal conflict of interest regulations; and (ii) specify time period(s) for the Subrecipient to report all identified Financial Conflicts of Interest to BCW. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Research Staff Members are subject to this Conflict of Interest Policy and will disclose Significant Financial Interests that are directly related to the Subrecipient's work for BCW in accordance with this Policy.

3. DUTY TO DISCLOSE

3.1 Ongoing Duty to Disclose

Each BCW Research Staff Member has an ongoing obligation to disclose Significant Financial Interests (including actual or potential Financial Conflicts of Interest) to the Director of Research Administration or the EVP of Research on a BCW-approved Disclosure Statement.

3.2 Disclosure Statements

A Research Staff Member may submit an updated Disclosure Statement at any time, but must submit an updated Disclosure Statement to Director of Research Administration or the the EVP of Research as specified below:

- (a). Upon initiation of employment;
- (b). Annually, as instructed by BCW;¹¹
- (c). Prior to the date of submission a proposal/application for PHS-funded research;¹²
- (d). Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest;¹³ and
- (e). If added as a new Research Staff Member to an ongoing PHS-funded research project;
- (f). Upon request of the EVP of Research, the Director of Research Administration, or the RCOI Committee.

4. RESEARCH CONFLICT OF INTEREST REVIEW

4.1 Review of Significant Financial Interests

The Director of Research Administration will review all disclosed Significant Financial Interests under \$5,000 (except for consulting, employment compensation and intellectual property) within sixty (60) days of disclosure. The RCOI Committee will review all other disclosed Significant Financial Interests within sixty (60) days of disclosure. Disclosure Statements related to PHS-funded research will be reviewed as soon as practicable and prior to expenditure of any PHS funds for such research. The

Director of Research Administration or the RCOI Committee will determine whether Significant Financial Interests constitute FCOIs.¹⁴ A Significant Financial Interest is an FCOI if the Director or Committee finds that:

- (a). the Research Staff Member has the ability to directly affect the design, conduct, or reporting of the research; and
- (b). an independent observer might reasonably question whether the Research Staff Member's actions or decisions may be unduly influenced by his/her Financial Interests.

If an FCOI exists, the Committee will:

- (a). determine whether the FCOI is related to PHS-funded research;
- (b). develop, implement and document, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI (see Section 5);¹⁵
- (c). submit required FCOI reports, as necessary (See Section 6).

4.2 Review of Unaddressed Significant Financial Interests

An unaddressed Significant Financial Interest is a Significant Financial Interest that was not disclosed to or addressed by the RCOI Committee in a timely manner. For example, a Research Staff Member failed to disclose a Significant Financial Interest, or the RCOI Committee neglected to address a disclosed Significant Financial Interest. If an unaddressed Significant Financial Interest arises, the RCOI Committee will review the Significant Financial Interest in accordance with Section 4.1 to determine whether the Significant Financial Interest is an FCOI. If the unaddressed Significant Financial Interest is determined to be an FCOI, the RCOI Committee will also perform a retrospective review (see Section 4.3).¹⁶

4.3 Retrospective Review of Unaddressed FCOIs.

An unaddressed FCOI is an FCOI that was not identified or managed in a timely manner, including failure by a Research Staff Member to disclose an FCOI, failure by the RCOI Committee to review or manage the FCOI; or failure by the Research Staff Member to comply with a FCOI management plan. If an unaddressed FCOI arises, the RCOI Committee shall, within one-hundred-twenty (120) days of the Research Committee's determination of noncompliance, complete a retrospective review of the Research Staff Member's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.¹⁷

- (a). The RCOI Committee will document the retrospective review. Such documentation shall include all of the following key elements:
 - i. Project number and title;
 - ii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - iii. Name of the Research Staff Member with the FCOI;
 - iv. Name of the entity with which the Research Staff Member has an FCOI;

- v. Reason(s) for the retrospective review;
 - vi. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - vii. Findings of the review; and
 - viii. Conclusions of the review.¹⁸
- (b). If no bias is found, the EVP of Research shall submit an updated FCOI report to the PHS Awarding Component (see Section 6.2) and ensure that the RCOI Committee has implemented a management plan (see Section 5).¹⁹ Thereafter, the Institution will submit FCOI reports annually (see Section 6.3).
- (c). If bias is found, the RCOI Committee will: (1) ensure that the RCOI Committee has implemented a management plan (see Section 5); (2) notify the PHS Awarding Component promptly; (3) submit an updated FCOI report to the PHS Awarding Component (see Section 6.2); and (4) submit a mitigation report to the PHS Awarding Component (see Section 6.4).²⁰

5. MANAGEMENT PLANS

5.1 Development and Documentation

If the Director of Research Administration or the RCOI Committee determines that an FCOI exists, the RCOI Committee will develop, implement, and document a management plan that specifies the actions that have been, and shall be, taken to manage such FCOI.²¹ Such management plan shall include the following key elements:

- (a). Role and principal duties of the conflicted Research Staff Member in the research project;
- (b). Conditions of the management plan;
- (c). How the management plan is designed to safeguard objectivity in the research project;
- (d). Confirmation of the Research Staff Member's agreement to the management plan;
- (e). How the management plan will be monitored to ensure Research Staff Member compliance; and
- (f). Other information as needed.

5.2 Conditions and Restrictions

Examples of conditions or restrictions that might be imposed to manage a Research Staff Member's FCOI include, but are not limited to:²²

- (a). Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- (b). For research projects involving human subjects research, disclosure of the FCOI 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 the research plan;
- (e). Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (f). Reduction or elimination of the FCOI (e.g., sale of an equity interest);
- (g). Severance of relationships that create the FCOI; and/or
- (h). Any other restrictions that the RCOI Committee determines to be appropriate.

5.3 Monitoring and Compliance

All Research Staff Members are expected to comply with management plans established by the RCOI Committee. The RCOI Committee shall monitor Research Staff Member compliance with management plans on an ongoing basis, until the completion of the research project.²³

6. PHS AWARDING COMPONENT REPORTS

6.1 Initial FCOI Reports

Prior to the expenditure of PHS funds related to a PHS-funded research project, the EVP of Research will provide FCOI reports to the PHS Awarding Component²⁴ The FCOI report need not include FCOIs eliminated prior to the expenditure of PHS-awarded funds.²⁵ The FCOI shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of FCOIs and to assess the appropriateness of the RCOI Committee's management plan.²⁶ The Initial FCOI Report shall include all of the following for each FCOI:²⁷

- (a). Project number;
- (b). Project Director/Principal Research Staff Member, or Contact PD/PI if a multiple PD/PI model is used;
- (c). Name of the Research Staff Member with the FCOI;
- (d). Name of the entity with which the Research Staff Member has a FCOI;
- (e). Nature of the Significant Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (f). Value of the Significant Financial Interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (g). Description of how the Significant Financial Interest relates to the PHS-funded research;
- (h). Basis for the RCOI Committee's determination that the Significant Financial Interest conflicts with such research;

- (i). Description of the key elements of the management plan, including (a) role and principal duties of the conflicted Research Staff Member in the research project; (b) conditions of the management plan; (c) how the management plan is designed to safeguard objectivity in the research project; (d) confirmation of the Research Staff Member's agreement to the management plan; and (e) how the management plan will be monitored to ensure Research Staff Member compliance; and (f) other information as needed.²⁸

6.2 Updated FCOI Reports

For any new FCOI identified during an ongoing PHS-funded research project, but subsequent to submission of the initial FCOI report (e.g., a Research Staff Member is new to the research project or a Research Staff Member develops a new FCOI), the EVP of Research shall provide to the PHS Awarding Component, within sixty (60) days, an updated FCOI report regarding the new FCOI (see Section 4.2.2, and ensure that the RCOI Committee has implemented a management plan (see Section 5).²⁹

6.3 Annual FCOI Reports

For any FCOI previously reported by the EVP of Research, with regard to an ongoing PHS-funded research project, the EVP of Research shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of each FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether each FCOI is still being managed, or explain why the FCOI no longer exists. The EVP of Research shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.³⁰

6.4 Mitigation Reports

For any unaddressed FCOI identified during an ongoing PHS-funded research project, the EVP of Research shall also submit a mitigation report that includes, at a minimum:

- (a). the key elements set forth in Section 4.3 above;
- (b). a description of the impact of the bias on the research project; and
- (c). the RCOI Committee's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).³¹

7. RECORDS, ACCESSIBILITY

7.1 Records

For at least three years from the date the final expenditures report is submitted to the PHS (or as otherwise required), the RCOI Committee will maintain records relating to all Research Staff Member disclosures of Financial Interests and the RCOI Committee's review of, and response to, such disclosures (whether or not a disclosure resulted in the RCOI Committee's determination of an FCOI)

and all actions under this Policy.³² The RCOI Committee will make information available, promptly upon request, to the U.S. Department of Health and Human Services relating to any Research Staff Member disclosure of financial interests and the RCOI Committee's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.³³

7.2 Public Accessibility

This Conflict of Interest Policy will be made available on BCW intranet and internet websites.³⁴ Within five (5) business days of BCW's receipt of written request from any requestor, the Compliance Officer/Corporate Counsel will provide a written response describing FCOIs related to PHS-funded research held by BCW Research Staff Members.³⁵ The written response shall include, at a minimum, the following:

- (a). the Research Staff Member's name, title and role with respect to the research project;
- (b). the name of the entity in which the Significant Financial Interest is held;
- (c). the nature of the FCOI; and
- (d). the approximate dollar value of the FCOI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.³⁶

8. POLICY REVIEW, EDUCATION, VIOLATIONS

8.1 Policy Review & Amendment

Corporate Counsel and the RCOI Committee will review this Policy as needed and at least every two years. Questions regarding the implementation of this Policy should be directed to BCW's EVP of Research or Corporate Counsel/Compliance Officer.

8.2 Education

New BCW Research Staff Members will complete a training session that addresses the content of this Policy, the Research Staff Member's obligations regarding the disclosure of Financial Interests, and the substance of applicable federal regulations regarding conflicts of interest during the orientation process and prior to engaging in research related to any PHS-funded grant. Thereafter, all BCW Research Staff Members will repeat the required training: (1) at least every four (4) years; (2) if and when BCW revises this Policy (if such changes materially affect the requirements for Research Staff Members); and (3) if and when BCW determines that the Research Staff Member is not in compliance with this Policy.³⁷

8.3 Violations

Failure to comply with the provisions of this Conflict of Interest Policy may result in discipline, up to an including termination of employment.³⁸

Replaces: Policy dated February 14, 2011
Review Period: Every two years
Approvals: July 31, 2012, Recommended by the BCW Compliance Committee
September 19, 2012, Approved by the BCW Board of Directors
February 12, 2015, Amendments approved by the RCOI Committee
March 18, 2015, Amendments approved by the BCW Board of Directors

¹ 42 CFR § 50.603; 42 CFR 94.3.

² 42 CFR § 50.603. BCW's Disclosure Statement requires Research Staff Member's to specify the details reimbursed/sponsored travel, which includes, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The BCW RCOI Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

³ 42 CFR § 50.603; 42 CFR § 50.604(f)

⁴ 42 CFR § 50.604(d).

⁵ 42 CFR § 50.603.

⁶ 42 CFR § 50.603.

⁷ 42 CFR § 50.603.

⁸ 42 CFR § 94.3.

⁹ 42 CFR § 50.604(c)(1)(i)-(ii).

¹⁰ 42 CFR § 50.604(c)(1)(iii).

¹¹ 42 CFR § 50.604(e)(2).

¹² 42 CFR § 50.604(e)(1).

¹³ 42 CFR § 50.604(e)(3).

¹⁴ 42 CFR § 50.604(f)

¹⁵ 42 CFR § 50.604(g) 42 CFR § 50.605(a)(3).

¹⁶ 42 CFR § 50.605(a)(3).

¹⁷ 42 CFR § 94.5(a)(3).

¹⁸ 42 CFR § 50.605(a)(3)(ii)(B).

¹⁹ 42 CFR § 50.605(a)(3)(iii); 42 CFR § 50.604(c)(2); 42 CFR § 50.604(h). 42 CFR § 50.605(b)(1)

²⁰ 42 CFR § 50.605(a)(3)(iii); 42 CFR § 50.604(c)(2); 42 CFR § 50.604(h). 42 CFR § 50.605(b)(1) 42 CFR 50.605(b)(2).

²¹ 42 CFR § 50.605(a)(1). 42 CFR § 50.605(b)(1)

²² 42 CFR § 50.605(a)(1).

²³ 42 CFR § 50.605(a)(4).

²⁴ 42 CFR § 50.604(c)(2); 42 CFR § 50.604(h). 42 CFR § 50.605(b)(1); 42 CFR § 90.5(b)(1)

²⁵ 42 CFR § 94.5(b)(1).

²⁶ 42 CFR § 94.5(b)(3).

²⁷ 42 CFR § 94.5(b)(3)(i)-(vi).

²⁸ 42 CFR § 50.605(b)(3).

²⁹ 42 CFR § 50.604(c)(2); 42 CFR § 50.604(h). 42 CFR § 50.605(b)(1)

³⁰ 42 CFR § 50.605(b)(4).

³¹ 42 CFR § 50.605(a)(3)(iii).

³² 42 CFR § 50.604(i).

³³ 42 CFR § 50.604(k)(4).

³⁴ 42 CFR § 50.604 requires BCW to make this Policy available via a publicly accessible website.

³⁵ 42 CFR § 50.605(a)(5)(C)(ii).

³⁶ 42 CFR § 50.605(a)(5)(ii).

³⁷ 42 CFR § 50.604(b)

³⁸ 42 CFR § 50.604(j); 42 CFR § 50.604(k)(2).