

Title:	Financial Conflict of Interest in Research				
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Approver(s):	BSWH Corporate Compliance Committee				
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SCOPE

This Policy applies to any person, regardless of title or position (each, an Investigator as used herein) who participates in the design, coordination, conduct, or reporting of research on behalf of Baylor Scott & White Health or any of its Controlled Affiliates (collectively, the Institution).

DEFINITIONS

When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.

Awarding Component – PHS Awarding Components includes all agencies that report under PHS, including; Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services (HRSA), Indian Health Service (IHS), National Institutes for Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Controlled Affiliates – Baylor Scott & White Health has more than 50% ownership, directly or indirectly, of the stock, partnership interest, membership interest, profits or capital interest in a corporation, partnership or limited liability company, or beneficial interest in a trust. Includes having the power to appoint and remove, directly or indirectly, a majority of a nonprofit's or for-profit's governing body. This definition, unless otherwise indicated, does not apply to Controlled Affiliates managed by a third party.

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.

Financial Interest – is anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI) – means a significant financial interest that the Baylor Scott & White Health Research Conflict of Interest Committee has deemed to be an FCOI related to the Investigator's Institutional Responsibilities.

Industry – Pharmaceutical, biotechnology, medical device, equipment supply and health care service providers and their employees, representatives and other agents, acting both on and off-premises of a BSWH System entity.

Institutional Responsibilities – means an Investigator's professional responsibilities to act on behalf of the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator – Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, including persons who are sub-grantees, contractors, consortium participants, collaborators, or consultants.

Management Plan – is an action plan that is directed by the Committee to a specific Investigator, when review of the SFI has been deemed to be a FCOI. The Management Plan addresses an Investigator's FCOI by reducing or

eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research is free of bias.

Research – Applies to basic and applied research (e.g., a published book or book chapter) and product development (e.g., a diagnostic test or drug) authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Remuneration - includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Manage – means taking action regarding a FCOI, to reduce or eliminate, to the extent possible, the potential for bias in the design, conduct, and reporting of research.

Mitigate – means taking action to eliminate the influence of bias that has occurred retrospectively in the design, conduct, or reporting of research.

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).

Senior/Key Personnel – means the Project Director/principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to PHS by the Institution under regulation.

POLICY

The principles stated in sections 1 to 4 apply to all Investigators regardless of the source of project funding.

1. Financial Disclosure

- 1.1. Investigator has a duty to submit and maintain a current financial disclosure (a) annually; and (b) within thirty days of discovering or acquiring a new financial interest (e.g. through purchase, marriage, or inheritance); (c) prior to starting a research project; and (d) prior to entering into an agreement with a third party regarding a research project.
- 1.2. Criteria required to complete a financial disclosure will be the same regardless of the source of research funding (e.g. PHS, NSF, NIH, FDA, private funds, institutional funds, commercial sponsor, or other).
- 1.3. Financial disclosure will include salaries and any Remuneration, Equity Interest, intellectual property rights and interests (e.g. patent, copyright) upon receipt of income related to such rights and interest, gifts, business entertainment, or sponsored travel received directly from Industry, a project sponsor, or vendor doing business with a Baylor Scott & White Health affiliated organization.
- 1.4. Investigators are to follow the BSWH Code of Conduct and at all times act in a manner consistent with his or her Institutional Responsibilities and shall exercise due care to avoid situations that create conflict between his or her private financial interests and those of the Institution.
- 1.5. Investigator financial interests includes: the interests of the Investigator, the Investigator's spouse, and all dependent children.

2. Institution Responsibilities

- 2.1. This Policy is to be published on the Institution's public website.
- 2.2. The Institution will conduct an annual survey to solicit Investigator disclosures of financial interests.

- 2.3. Investigator disclosures will be evaluated by the Institution to determine if the disclosure is related to the Investigator's Institutional Responsibilities.
- 2.4. Disclosures that are deemed related to the Investigator's Institutional Responsibilities will be further evaluated to determine if a Financial Conflict of Interest (FCOI) exists.
- 2.5. When an FCOI is identified, the Institution will issue a Management Plan appropriate to the (1) disclosed situation, (2) relatedness to Institutional Responsibilities, (3) Institutional policies, and (4) application of appropriate regulations and accreditation requirements.
- 2.6. The Institution shall promote and enforce Investigator compliance with Management Plans.

3. Research Conflict of Interest Committee (Committee) Responsibilities

- 3.1. The Committee will make a determination as to whether the disclosed arrangement is related to the research (biases or can be perceived to bias the Investigator's participation in research studies). Any such determination of bias constitutes an FCOI.
- 3.2. A Management Plan to reduce or eliminate FCOIs will be issued to the Investigator with the FCOI by the Committee.
- 3.3. Management Plans may include, but are not limited to, actions that require:
 - 3.3.1. Public disclosure of FCOIs (e.g., when presenting or publishing the research);
 - 3.3.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 3.3.3. 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;
 - 3.3.4. Modification of the research plan;
 - 3.3.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 3.3.6. Reduction or elimination of the financial interest (e.g., sale of an Equity Interest); or
 - 3.3.7. Severance of the relationship(s) that creates financial conflicts.
- 3.4. The Institution will document all identified FCOIs and issue a Management Plan to the Investigator.
- 3.5. Investigators are required to implement all aspects of the assigned Management Plan prior to the expenditure of any new project funds.
- 3.6. Management Plans are to be implemented immediately for newly identified FCOIs related to new or ongoing projects, unless timing is otherwise specifically directed by the Committee.
- 3.7. Stipulations outlined in Management Plans are to remain in effect for the life of study(ies), unless otherwise amended by direction of the Committee. In such cases, Investigators will be notified of such changes in writing.

- 3.8. All Management Plans issued by the COI Committee are reviewed and approved by designated members of the IRB prior to being issued. This is to assure that the Management Plan is sufficient to protect the rights, welfare, and safety of the individual subjects.
- 3.9. During the IRB review process for a new project or request for addition of new personnel, IRB staff will complete a COI checklist to assure that Management Plan stipulations are incorporated into the project appropriately prior to the start of the research or approval of new personnel.

4. Enforcement and Remedies

If during a retrospective review it is discovered that an Investigator failed to comply with this Policy or the stipulations of a Management Plan; and the failure appears to have biased the design, conduct or reporting of a research study, then appropriate corrective actions are to be taken by the Institution to mitigate the effects of said bias.

- 4.1 Any person who is found to have violated this Policy (for example by a failure to disclose a Significant Financial Interest or failed to implement the stipulations of a Management Plan) will be disciplined in accordance with the *BSWH Enforcement and Corrective Action Policy*.
- 4.2. Violations that constitute falsification in proposing, performing, reporting or reviewing research will be handled in accordance with the Institution's *Research Misconduct Policy* and the *BSWH Enforcement and Corrective Action Policy*.

5. Projects Funded by Public Health Service (PHS) or a PHS Awarding Component

PHS regulations set forth unique requirements that Investigators and Institutions must follow in the disclosure, management, and mitigation of conflict of interest related to PHS funded studies.

This section, 5, applies only to Investigators and Senior/Key personnel who participate in PHS funded research. These requirements are in addition to stipulations noted elsewhere in this Policy.

- 5.1. Disclosed financial interests will be evaluated by the Institution (designated members of the COI Committee) to determine if a Significant Financial Interest exists and if this interest is related to the PHS funded research. This must occur within sixty days of the Investigator's disclosure to the Institution.
- 5.2. Investigators of PHS funded research must accept and implement assigned Management Plans within 21 days of issuance of the plan.
- 5.3. Investigators who participate in PHS funded studies must disclose all travel accommodations (including arrangements related to any Institutional responsibility) that are paid and/or are reimbursed by commercial industry. PHS Investigators must seek approval for Industry-sponsored travel that involves travel outside the continental United States or lodging in excess of three nights or for Industry-sponsored travel that is not associated with research investigator meetings.
- 5.4. Identified Conflict of Interests for new PHS funded studies are to be addressed by the Institution and reduced, eliminated, and managed prior to spending any project funds.

5.5. Mitigation and PHS Reporting

- 5.5.1. The Institution is responsible for submitting initial and annual FCOI reports to the PHS awarding component in accordance with regulation.

- 5.5.2. Conflict of Interests that are identified after the start of a project will be mitigated by the Institution in a manner consistent with eliminating the impact of bias that may have occurred in the course of conducting research.
- 5.6. The Institution is responsible for completing retrospective reviews when there is non-compliance with the Institution's policy or PHS regulation.
- 5.7. FCOIs for Senior/Key Personnel who are working on PHS funded projects will be provided, upon request, to any member of the public. As required by regulation, the information provided upon request will include: (1) Investigator's name, (2) Investigator's title and role with respect to the research project, (3) the name of the entity in which the FCOI is held, (4) the nature of the FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria, etc.), and (5) 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.
- 5.8. The Institution will keep records of financial disclosures, related to PHS funded studies, and all actions taken by the Institution with respect to each conflicting interest as follows:
 - 5.8.1. For grants or cooperative agreements, - for at least three years from the date of submission of the final expenditures report or, where applicable, for other dates specified in 45 CFR 74.53(b) for different situations.
 - 5.8.2. For research contracts – for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4.
- 5.9. When engaging subrecipient organizations to carry out PHS funded research, the Institution will take reasonable steps and enforce all prescriptive requirements of law to ensure compliance of subrecipients to regulatory FCOI requirements.
 - 5.9.1. Investigators associated with subrecipient organizations are required to follow a conflict of interest program that is compliant with PHS regulations.
 - 5.9.2. All subrecipient agreements or contracts between the Institution and subrecipient organizations are to explicitly state whether subrecipient Investigators will follow the subrecipient organization's conflict of interest policies and procedures or the Institution's policy and procedures.
 - 5.9.3. When subrecipient organizations contract that Investigators will follow the Institution's conflict of interest policies and procedures, the subrecipient organization must also provide the full legal name of each Investigator who will be associated with the study and a valid email address, in a timely fashion such that the solicitation, completion, review and management of information can be addressed prior to expenditure of funds on a new study and within sixty days of any subsequently identified FCOI.
 - 5.9.4. The Institution is responsible for the reporting of all FCOIs to the PHS awarding component for all investigators working on PHS funded studies, including subrecipients.
- 5.10. Public Reporting of FCOIs related to PHS funded research.
 - 5.10.1. The Institution will respond within five business days of having received a written request for information regarding an Investigator's FCOIs (not SFIs) that are related to an individual's Institutional Responsibilities and when the Investigator is identified by the Institution as Senior/Key Personnel on PHS funded studies.

- 5.10.2. Requests for publicly available information must include the Investigator's name or the name of the PHS funded research and be mailed to:

Baylor Scott & White Research Institute
Office of Research Regulatory Affairs
3434 Live Oak Street
Dallas, TX 75204

- 5.11. Investigators who participate in PHS funded research will follow the mandatory training requirements promulgated by federal law, which states investigators will be trained on the Institution's FCOIs Policy. Training frequency is mandated by federal regulation and will be carried out as follows:

5.11.1. Anytime an Investigator is new to the organization, and

5.11.2. Every four years, and

5.11.3. Upon revision of the FCOIs policies or procedures in any manner that affects the requirements of Investigators, and

5.11.4. Any time an Investigator is found to be non-compliant with this Policy or has failed to implement a Management Plan assigned by the Conflict of Interest Committee.

- 5.12. Investigators who work on PHS funded research also must disclose the occurrence of any 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), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. The Investigator will be required to disclose, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) 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.

- 5.13. Additional Remedies for Non-Compliance of PHS Funded Research;

5.13.1. If an Investigator fails to comply with this FCOI Policy or a Management Plan that is related to PHS funded research; and the non-compliance appears to have biased the design, conduct or reporting of the PHS funded research, the Institution shall promptly notify the PHS awarding agency of the corrective action taken or to be taken to mitigate the risk of bias.

5.13.2. The Institution will work to ensure compliance with the PHS requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable PHS awarding agency. The PHS awarding agency may take its own action as it deems appropriate, which may include suspension of funding, or require the Institution to take further action to maintain objectivity of research.

- 5.14. A significant financial interest means: 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 Institutional Responsibilities:
- 5.14.1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 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 (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 measures of fair market value);
 - 5.14.2. 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 12 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
 - 5.14.3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
 - 5.14.4. Investigators must also disclose the occurrence of any 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 might not be readily available) related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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.
- 5.15 The term significant financial interest does not include the following types of financial interests: 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 to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; 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; or 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

PROCEDURE

None.

ATTACHMENTS

Research Conflict of Interests Committee Charter (BSWH.CMPL.RES.006.A1)

RELATED DOCUMENTS

BSWH Code of Conduct

BSWH Conflict of Interests Policy (BSWH.CMPL.ETH.001.P)

BSWH Vendor Sponsored Travel Policy (BSWH.CMPL.ETH.002.P)

BSWH Entertainment for Business Purposes Policy (BSWH.CMPL.ETH.003.P)

BSWH Gifts and Business Gratuities Policy (BSWH.CMPL.ETH.004.P)

BSWH Honorarium Policy (BSWH.CMPL.ETH.007.P)

BSWH Enforcement and Corrective Action Policy (BSWH.CMPL.OPS.004.P)

REFERENCES

None.

The information contained in this document should not be considered standards of professional practice or rules of conduct or for the benefit of any third party. This document is intended to provide guidance and, generally, allows for professional discretion and/or deviation when the individual health care provider or, if applicable, the "Approver" deems appropriate under the circumstances.

Attachment Name:	Research Conflict of Interests Committee Charter		
Attachment Number:	BSWH.CMPL.RES.006.A1	Last Review/Revision Date:	03/24/2016

PURPOSE

Management of conflict of interests (both financial and other) is important to Baylor Scott & White Health as well as Baylor Scott & White Research Institute. Due to regulatory and accreditation requirements, an entity level conflict of interest review process takes place for research in addition to the process which takes place at the BSWH Corporate level. The Research Conflict of Interest Committee (“Committee”) is a joint committee between BSWRI and BSWH that serves to promote objectivity in research by assisting in the administration of the Financial Conflict of Interest in Research policy.

MEMBERSHIP/TERMS OF APPOINTMENT

The Committee shall include at least six and no more than 12 members, appointed by the BSWRI President or designee. Each member’s appointment will be for an indefinite term until such time as the member resigns. If a member is unable to attend a meeting for six consecutive meetings, they may be asked to resign.

1. The following individuals are considered to be ex-officio voting members:
 - a. BSWH Chief Compliance Officer
 - b. BSWRI Chief Regulatory Officer
 - c. BSWH Research Integrity Officer

2. Additional members are determined as follows:
 - a. Representative from BSWRI Research Administration
 - b. At least two physician members as agreed upon by leadership from BSWRI and Corporate Compliance

3. The membership shall include the following representation:
 - a. Scientific expertise (including at least one physician member)
 - b. Research Administration/Operations including grants & contracts
 - c. Research Regulatory Affairs
 - d. BSWH Office of Corporate Compliance
 - e. Individual with training in a non-scientific area

An individual member may be considered to fulfill more than one of the above criteria.

4. The Committee will have two Co-Chairs as designated by BSWRI and BSWH Corporate Compliance. Administrative support will be shared by BSWRI and BSWH Corporate Compliance as needed.

CHARGE OF THE COMMITTEE

It is the responsibility of the Committee to:

- Review disclosures determined by BSWRI/BSWH policy and/or Federal regulations to be a significant financial interest.
- Evaluate relatedness of Investigator’s Institutional Responsibilities to the disclosed financial interest.

- If a disclosed financial interest is deemed to be related, then determine whether a Financial Conflict of Interest (FCOI) exists. If an FCOI exists, then the Committee is to stipulate actions, through a Management Plan, that effectively address the FCOI.
- Issue Management Plans and track Investigator acceptance of assigned plan.
- Notify the Institution's designated official of all actionable items that are to be reported to PHS or an awarding component.
- May provide guidance and direction concerning corrective actions related to non-compliance with the Financial Conflict of Interest in Research Policy or Federal regulations.
- Periodically review BSWRI/BSWH policies that are related to Committee responsibilities and recommend updates as necessary.

These responsibilities can be carried out by the Committee Co-Chairs, full membership or sub-committees as outlined in policy.

MEETINGS

Frequency

The Committee shall meet as often as needed to perform the above responsibilities in a time frame appropriate to assure compliance with regulations and BSWRI/BSWH policy, but no less than two times per year.

Quorum

A simple majority of the voting membership will constitute the necessary quorum in order to conduct official Committee business.

Committee Minutes and Documentation of Decisions

Minutes of each meeting of the full Committee will be prepared by a Co-Chair of the Committee and submitted to all members after the meeting.

Documentation of administrative decisions and/or sub-committee reports will be maintained by a Committee Co-Chair.