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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 ("SFI") related to an Investigator's Institutional Responsibilities that the Baylor Scott & White Health Research Integrity Officer ("RIO") has reasonably determined a) to be related to the Investigator's funded Research, b) could be affected by the funded Research or is an entity whose financial interest could be affected by the Research, and c) could directly and significantly affect the design, conduct, or reporting of the funded Research.

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.

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 NIH.

Research – means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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).

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.

Significant Financial Interest ("SFI") - 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:

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;
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
3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests that exceeds $5,000 in the 12 months preceding the disclosure; or
4. Reimbursed or sponsored travel that when aggregated exceeds $5,000 in the 12 months preceding the disclosure.

   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; unlicensed intellectual property that does not generate income; 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 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; 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

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 a financial disclosure (a) annually; and (b) within thirty days of discovering or acquiring a new Financial Interest (e.g. through purchase, marriage, or inheritance). The Investigator has a duty to maintain a current disclosure (a) prior to starting a Research project; (b) prior to entering into an agreement with a third party regarding a Research project; and (c) no later than the time of application for external funding.

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 any 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, or reimbursed or sponsored travel.

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 include: the interests of the Investigator, the Investigator's spouse, and all dependent children.

2. Institutional Responsibilities

2.1. The Institution will conduct an annual survey to solicit Investigator disclosures of Financial Interests.

2.2. Investigator disclosures will be evaluated by the Institution to determine if the disclosure is related to the Investigator's Institutional Responsibilities.

2.3. Disclosures that are deemed related to the Investigator's Institutional Responsibilities will be further evaluated to determine if an FCOI exists.

2.4. 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.

2.5. The Institution shall promote and enforce Investigator compliance with Management Plans.

3. Research Conflicts of Interest Committee ("Committee") Responsibilities

3.1. The RIO 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 potential bias constitutes a conflict of interest that needs to be eliminated or Managed. Standard Management Plans previously established by the Committee may be issued by the RIO.

3.2. A Management Plan to reduce or eliminate conflicts determined by the RIO to be 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; to staff members working on the project; to the Institution's Institutional Review Board(s)];

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. Investigators are required to implement all aspects of the assigned Management Plan prior to the expenditure of any new project funds.

3.5. Management Plans are to be implemented immediately for newly identified conflicts related to new or ongoing projects, unless timing is otherwise specifically directed by the Committee.

3.6. 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.

3.7. All issued Management Plans are reviewed and approved by designated members of the IRB prior to engagement of the personnel in related Research. This is to assure that the Management Plan is sufficient to protect the rights, welfare, and safety of the individual subjects.

3.8. 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 failure to implement the stipulations of a Management Plan) will be disciplined in accordance with the BSWH Reporting and Addressing Compliance Concerns 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 Reporting and Addressing Compliance Concerns Policy.

5. Projects Funded by 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 conflicts 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. Investigators are required to disclose their foreign and domestic SFIs (and those of their spouse and dependent children) related to their Institutional Responsibilities. Investigators also 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 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 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. 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. The Research Integrity Officer will determine if further information is needed to determine whether the travel constitutes an FCOI with the PHS funded Research.

5.2. Prior to the expenditure of funds, disclosed Financial Interests will be evaluated by the Institutional Research Integrity Officer to determine if an SFI exists and if this interest is related to the PHS funded Research and, if so related, whether the SFI is an FCOI. This must occur within sixty days of the Investigator's disclosure to the Institution when the Investigator is new to participating in the Research project or when an existing Investigator discloses a new SFI.

5.3. Investigators of PHS funded Research must accept and implement assigned Management Plans within 21 days of issuance of the plan. For any FCOI identified for an Investigator new to participating in the Research project or for an existing Investigator with a newly disclosed or otherwise identified SFI, the Institution will implement, on at least an interim basis, a Management Plan that specifies the actions that have been and will be taken to Manage the FCOI going forward. The Institution will take actions as necessary to Manage FCOIs and monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the funded Research.

5.4. Identified Conflicts of Interest 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, revised, and annual FCOI reports to the PHS Awarding Component in accordance with regulation (i.e., prior to expenditure of funds, within 60 days of identification for a newly participating Investigator or new/newly identified FCOI for existing Investigators, at least annually, and after a retrospective review to update a previously submitted report).

5.5.2. Conflicts of Interest that are identified after the start of a project will be Mitigated within 60 days 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 within 120 days when there is non-compliance with the Institution's policy or PHS regulation (e.g., failure to disclose or manage an FCOI or failure to comply with an FCOI Management Plan). The PHS Awarding Component will be promptly notified if bias is found with the design, conduct or reporting of the PHS funded Research and submit the required mitigation report. The mitigation report will include key elements documented in the retrospective review (project number, title, and PD/PI; name of Investigator with FCOI and name of the entity with which they have the FCOI; reason for the retrospective review; detailed methodology, findings, and conclusion of the review), a description of the impact of the bias on the Research project and the Institution's plan of actions taken to eliminate or Mitigate the effect of the bias.

5.7. Should the U.S. Department of Health and Human Services determine for a funded project of clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical

device, or treatment that was designed, conducted, or reported by an Investigator with an FCOI that was not Managed or reported by the Institution as required by regulation, the Investigator will be required to: (1) disclose the FCOI in each public presentation of the results of the Research, and (2) request an addendum to previously published presentations.

5.8. The Institution will keep records of financial disclosures related to PHS funded studies, review of and response to such disclosures, and all actions taken by the Institution with respect to this Policy or retrospective review:

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 2 CFR 200.334 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 conflicts 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 conflicts of interest policies and procedures (that are compliant with PHS regulations) or the Institution's policy and procedures.

5.9.3. When subrecipient organizations contract that Investigators will follow the Institution's conflicts 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. Subrecipient disclosures must include SFIs that are directly related to the subrecipient's work for the Institution.

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. When subrecipient organizations will follow their own organization's conflicts of interest policies and procedures, the subrecipient agreements or contracts will include a requirement for the subrecipient to report identified FCOIs for its Investigators in a timeframe that allows the awardee Institution sufficient time to review, Manage and report identified FCOIs per regulation.

5.10. Public Accessibility related to PHS funded Research:

5.10.1. This Policy is to be published on the Institution's public website.

5.10.2. SFIs for Senior/Key Personnel who are working on PHS funded projects will be provided, upon request, to any member of the public within five business days of a request if the SFI meets the following criteria: (1) The SFI was disclosed and is still held by the personnel, (2) the Institution determines the SFI is related to the PHS funded Research, and (3) the Institution determined the SFI is a FCOI. 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 SFI is held, (4) the nature of the SFI (e.g. equity, consulting fees, travel reimbursement, honoraria, etc.), and (5) the approximate dollar value of the SFI 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. The requestor will be informed the information

provided is current as of the date provided and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new FCOI, which should be subsequently requested.

5.10.3. 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. Training: Investigators who participate in PHS funded Research will follow the mandatory training requirements, which includes training on the Institution's FCOI Policy, the Investigator's responsibilities regarding disclosure of all foreign and domestic SFIs, and the regulations at 42 CFR Part 50 Subpart F. Training frequency is mandated by federal regulation and will be carried out as follows:

5.11.1. Prior to engaging in Research related to any PHS-funded grant,

5.11.2. Every four years, and

5.11.3. Immediately, if:

5.11.3.1. This Policy or procedures are revised in any manner that affects the requirements of Investigators,

5.11.3.2. An Investigator is new to the Institution, or

5.11.3.3. Any time an Investigator is found to be non-compliant with this Policy or Management Plan.

PROCEDURE

None.

ATTACHMENTS

None.

RELATED DOCUMENTS

BSWH Code of Conduct
BSWH Conflicts of Interest Policy (BSWH.CMPL.ETH.001.P)
BSWH Reporting and Addressing Compliance Concerns Policy (BSWH.CMPL.OPS.003.P)
BSWH Research Misconduct Policy (BSWH.CMPL.RES.007.P)

REFERENCES

42 C.F.R. Part 50 Subpart F – Promoting Objectivity in Research
NIH Financial Conflict of Interest Tutorial