Baptist Health South Florida

POLICY NO.: 1300.03
TYPE: Administrative

POLICY TITLE: Individual Financial Conflict of Interests (FCOI) in Research

SUMMARY & PURPOSE:
Conflicts of interest in research occur when a person has the opportunity to influence research activities in ways that could result in personal gain. It is the policy of Baptist Health South Florida and its affiliated entities ("BHSF") to require that Investigators avoid financial interests or relationships that could result in a conflict so that their research-related activities and interests do not conflict with their BHSF responsibilities including, in part, their obligations to BHSF patients and to research participants. The purpose of this policy and procedure is to promote objectivity and maintain public trust in research by establishing guidelines and procedures for reporting and managing conflicts of interest related to research. For the purposes of this policy, a financial conflicts of interest exists when it is determined that an investigator has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research performed under Baptist Health South Florida (BHSF) oversight.

POLICY:

1. Investigators shall certify as part of a formal conflict of interest process that they have read the BHSF FCOI policy and shall conduct their research in a manner that promotes objectivity in research. To the extent there is the appearance of, potential for, or actual conflicts of interest, Investigators shall disclose the apparent, potential or actual conflict(s) of interest in accordance with the procedures of this policy and participate in a conflict of interest management plan.

2. Definitions:

A. Conflict of Interest in Research Committee (COIRC): A group of individuals who have primary authority, on behalf of BHSF, to identify, review and manage actual and potential individual conflicts of interest in research. The COIRC includes representatives of the Center for Research & Grants, BHSF Institutional Review Board (IRB) Management Department, Audit and Compliance Department, Legal Department, and additional departments by COIRC invitation.

B. Disclosure: an Investigator's disclosure of financial interests to the Institution based on his or her institutional responsibilities.

C. Financial Conflict of Interest (FCOI): a Significant Financial Interest (SFI, as hereinafter defined) that is related to a research project that could directly and significantly affect the design, conduct, or reporting of the research.

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

E. Investigator: Includes the principal Investigator and any other person responsible for the design, conduct, or reporting of research. This would generally include the Principal Investigator, and individuals that are either designated as Senior/Key Personnel (as defined herein), or other individuals identified by the Principal Investigator as being responsible for the design, conduct or reporting of the research project.

F. Institutional Responsibilities: an Investigator's professional responsibilities on behalf of or related to BHSF, which may include employment and/or contractual obligations, research, research consultation, teaching, clinical and professional services, institutional committee memberships, and service on panels such as Institutional Review Boards (IRBs or data and safety monitoring boards (DSMB)).

G. Management Plan: taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

h. Project Director (PD)/Principal Investigator (PI): The person(s) designated in the project application submitted to BHSF to have the appropriate level of authority and responsibility to direct the proposed project or program.

i. Public Health Services (PHS): A division of the Department of Health and Human Services (HHS). PHS includes such components as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC) , the Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), and National Institutes of Health (NIH).

j. Remuneration: Anything of monetary value received from an entity for services (e.g. consulting fees, honoraria, paid authorship); equity interest including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

k. Research: Any systematic investigation that is designed (in whole or in part) to develop or contribute to generalizable knowledge or the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration (FDA) as part of an application for a research or marketing permit.

l. Reviewable by BHSF: Activity for which, by virtue of regulatory or BHSF requirements, BHSF approval must be sought. To this end, BHSF approval may be sought, for example, from BHSF Institutional Review Board (IRB), BHSF Award Review Board (ARB), or administrative approval from a BHSF entity at which research may be conducted.

m. Senior/Key Personnel: The Project Director (PD) and/or the Principal Investigator (PI) and any other person identified as senior or key personnel in an application, progress report, or any other report or form submitted to BHSF for review.

n. Small Business Innovation Research (SBIR) Program: A research program for small business that is established by the Awarding Components of the Public Health Service (PHS) and certain other Federal agencies under Pub. L. 97–219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102–564.

o. Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the Investigator and/or those of the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities;

    i. Publicly Traded Entity: Any remuneration received from the entity in the twelve months preceding the disclosure and any equity interest in the entity as of the date of disclosure valued, when aggregated, in excess of $5,000;

    ii. Non-Publicly Traded Entity: Any remuneration received from the entity in the twelve months preceding the disclosure that, when aggregated, exceeds $5,000, or any equity interest (e.g., stock, stock option, or other ownership interest) the Investigator or the Investigator's spouse or dependent children holds in the non-Publicly Traded Entity;

    iii. Intellectual Property (IP): Any IP rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

    iv. Reimbursed or Sponsored Travel: Any reimbursed or sponsored travel (i.e., travel 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 the Investigator's Institutional Responsibilities.

Excluded from this term:

    i. Salaries or other remuneration from BHSF or a subsidiary of BHSF while the Investigator is employed or otherwise appointed by BHSF including IP rights assigned to BHSF and agreements to share in royalties related to such rights;

    ii. Any ownership interest(s) in a BHSF subsidiary;

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, an Institution of higher education as defined in at 20 U.S.C. 1001(a), and academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education, and

v. Income from service on advisory committees or review panels for a Federal, State, or local government agency, an Institution of higher education as defined in at 20 U.S.C. 1001(a), and academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; and

vi. 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.

p. Sub-recipient: For any PHS-funded research where BHSF is the prime awardee, any individual or entity that has entered into an agreement with BHSF as a subgrantee, subcontractor, collaborator, contractor, or consultant who will be involved in the research and is accountable to BHSF for outcomes and compliance matters, and to which BHSF passes through federal funds

SCOPE/APPLICABILITY:

This policy applies to all Investigators participating in research activities at Baptist Health South Florida. Subcontractors, subgrantees and collaborating Investigators must also comply with this policy. Compliance with this policy does not preclude persons subject to it from meeting the requirements of the following policies, as applicable:

- BHSF-454, Physician Conflict of Interest Policy – Physician Employees,
- BHSF-827, Employee Conflict of Interest, and
- BHSF-834.03, Financial Conflict of Interest.

PROCEDURES TO ENSURE COMPLIANCE:

1. **Disclosure and Education Requirements:**
   a. Each Investigator must comply with the BHSF Financial Conflicts of Interest in Research policy by disclosing any Significant Financial Interest(s) (SFIs) (and those of his/her spouse or dependent children) that reasonably appear to be related to the Investigator's Institutional responsibilities by completing a Research Financial Disclosure Form (Attachment A) as follows:
      i. Prior to submitting research studies to the IRB and/or, prior to submitting an application for funding; regardless of the source of funding.
      ii. At least annually
      iii. Upon acquisition or discovery of a new SFI, or if the value of a previously-disclosed financial interest changes such that it constitutes a SFI, or a previously-disclosed SFI increases in a significant manner. It is the Investigator's responsibility to submit an updated Research Financial Disclosure Form within 30 days, providing any information that was not disclosed previously.
   b. An Investigator must complete training on the BHSF FCOI Policy and Federal FCOI regulations:
      i. prior to engaging in research
      ii. not less frequently than once every three years thereafter

iii. when this policy has been revised such that the Investigators' responsibilities have changed, or
iv. when BHSF deems that any such training is required.

c. All Investigators will be required to verify that they have a current Research Financial Disclosure Form on file at the time of application of the Institutional Review Board (IRB).

2. **Review of Research Financial Disclosure Forms:**

a. The Research Compliance Administrator or designee will administratively review the Research Financial Disclosure Forms to assess the relationship of the disclosed SFI (if any) to the Investigator's research to determine which SFI(s) is/are related to the research. An assessment of relatedness will be made based on information provided by the Investigator and any/or any other facts deemed relevant. Prior to the expenditure of any funds and during the course of an initiated project, within 60 days of a new/updated disclosure, the Research Compliance Administrator or designee must review an Investigator's disclosure of SFI and determine if a FCOI exists, based on BHSF policy
b. The COIRC will meet as required, but not less frequently than quarterly, to evaluate research financial disclosure forms with disclosed SFI(s) deemed related to ongoing or proposed research and assist in determining actions required to manage any actual or potential conflicts.
c. For all determined FCOI, the Research Compliance Administrator or designee will develop a management plan as instructed by the COIRC and in accordance with the requirements of 42 CFR 50, Subpart F. Conditions or restrictions that the COIRC may impose to manage conflicts of interest include, but are not limited to, the following:
    i. Public disclosure of financial conflict(s) of interest;
    ii. Monitoring of research by independent reviewers;
    iii. Modification of the research proposal or plan;
    iv. Disqualification from participation of the Investigator in all or a portion of the research;
    v. Divestiture by the Investigator of the financial interest(s); and
    vi. Severance of relationships by the Investigator that create actual or potential conflicts.
d. As instructed by and on behalf of the COIRC, Research Compliance will send the Management Plan to the Investigator and to others as appropriate (for example, the Investigator's IRB, Grants Administration, etc).
e. If the Investigator disputes the Management Plan, he or she can request reconsideration by the COIRC. To request a reconsideration, the Investigator must
    i. draft a letter detailing the reasons for the request and proposed edits to the plan,
    ii. collect all relevant supporting documents, and
    iii. submit the letter and the supporting documents to Research Compliance. Research Compliance will forward the request to the COIRC for review.
f. Once finalized by the COIRC, the Investigator must acknowledge receipt of and agree to comply with the Management Plan.
g. After the Management Plan is agreed to by the Investigator, the Management Plan will be tracked and monitored by Research Compliance.
h. To the extent that an Investigator fails to follow the requirements of the Management Plan or the Management Plan fails to address the requirements of this policy, the COIRC may review and revise the Management Plan or any of its requirements as necessary, or impose additional requirements or sanctions that it determines reasonably necessary to achieve the purposes of this policy.

i. The Research Compliance Administrator or designee will maintain records relating to an Investigator's disclosure of financial interests and review of and response to such disclosures (whether or not a disclosure resulted in the determination of a FCOI) and actions under this policy or retrospective review, if applicable for at least three (3) years from the date that the final expenditures report is submitted to the sponsor (if applicable).

3. **Reporting of SFIs**

If a BHSF employee who is not an Investigator becomes aware of an Investigator's SFI:

i. The employee must report the information to a member of management or the Audit and Compliance Department. Contact information and available resources are listed in the Code of Ethics. The recipient will take the appropriate steps to ensure compliance with the disclosure requirements set forth in this policy.

ii. If a report of SFI is made via the Compliance Hotline the procedures set forth in BHSF-823. *Compliance Hotline*, will be followed.

4. **PHS-Funded Research:**

The following additional requirements apply to all research funded by the PHS and any PHS awarding component including the National Institute of Health (NIH) with an issue date of the Notice of Award that is subsequent to August 24, 2012 and to solicitations issued and contracts awarded subsequent to August 24, 2012:

a. BHSF shall report to the PHS-awarding component the existence of any SFI it found conflicting:
   i. Prior to the expenditure of funds under a PHS-funded component,
   ii. Annually while the PHS research project is funded via BHSF
   iii. Within sixty (60) days from identifying FCOI of an Investigator who is new to the PHS-funded research project
   iv. Within sixty (60) days from identification of new FCOI of Investigators already on a PHS-funded project, and
   v. Following a retrospective review to update a previously-submitted report, if appropriate. Said report will include
      1) the name of the Investigator with the FCOI
      2) the identity of the entity with which the Investigator has the FCOI,
      3) the value of the financial interest,
      4) the nature of the financial interest, and
      5) a description of how the conflict relates to the award.

b. Upon request for additional information from a PHS-awarding component, BHSF shall make information available to the PHS-awarding component regarding SFI BHSF found conflicting relating to the research that is the subject of the award, and how those interests have been managed, reduced, or eliminated to protect the research from bias.

c. If an SFI was not disclosed timely by an Investigator involved in PHS-funded research or if any such SFI was not previously reviewed by BHSF, the Investigator shall submit an updated RFDF and BHSF shall review any SFI disclosed in accordance with this policy. If it is determined that any FCOI exist, a Management Plan will be implemented within sixty (60) days from initially identifying any such SFI.

d. If BHSF becomes aware of a failure of an Investigator to comply with this policy that has biased the design, conduct, or reporting of PHS-funded research, BHSF shall,
   i. as appropriate and necessary, promptly notify the PHS-awarding component of the matter

ii. complete and document a retrospective review within one hundred and twenty (120) days from identification of said noncompliance.

e. BHSF will advise the PHS-awarding component on any proposed action including; for example, taking additional measures intended to maintain appropriate objectivity in the funded project. Notwithstanding the foregoing, BHSF may take any other actions it deems appropriate to resolve or eliminate any non-compliance at issue.

f. For Investigators whose PHS-funded research project aims at evaluating the safety or effectiveness of a drug, medical device, or treatment: if the Department of Health and Human Services (HHS) 1) finds that their FCOI was not managed or reported per the regulation and 2) so requires, BHSF shall require these Investigators to

i. disclose their FCOI in each public presentation of the results of said project and

ii. request an addendum to previously published presentations of the results of the project, if applicable and necessary.

5. **Subrecipients:**

a. Where BHSF is a prime awardee on PHS- funded Research, BHSF will take reasonable steps to ensure that:

i. Subrecipient(s) are in compliance with the FCOI Regulations,

ii. Subrecipient Investigator FCOI are reported, and

iii. Monitoring Subrecipient Investigator(s) management plans.

b. A written agreement will be entered into with the Subrecipient specifying whether BHSF or Subrecipient's FCOI Policy will apply and will also contain all items required by the FCOI Regulations to ensure that Subrecipient and any Subrecipient Investigator(s) provide all information necessary to BHSF to enable BHSF to make required reports to PHS in a timely manner.

c. BHSF's FCOI Policy shall apply to Subrecipient Investigators unless the Subrecipient Institution certifies that its FCOI policy complies with the FCOI Regulations and BHSF determines in the written agreement that it will defer to Subrecipient's FCOI policy.

i. If the Subrecipient appropriately certifies that its policy complies with the FCOI Regulations, the Subrecipient's FCOI Policy will apply to Subrecipient Investigator(s), however, the written agreement between Subrecipient and BHSF will specify timeframes for reporting FCOIs to BHSF adequate for BHSF to file timely reports with PHS.

ii. If BHSF's FCOI Policy applies, the written agreement between BHSF and Subrecipient will also provide timeframes for Sub-recipient to submit all required SFI disclosures and other required notifications to BHSF adequate for BHSF to comply with its FCOI Policy and to file timely reports with PHS.

d. Before a proposal to a PHS agency may be submitted, all known Subrecipient Investigators must disclose their outside financial interests with BHSF to BHSF Research Compliance.

6. **Public Accessibility**:

a. This policy shall be available via BHSF's publicly accessible website.

b. For PHS funded research, BHSF shall make information concerning SFIs that meet the criteria below available to the public, upon written request for such information:

i. SFI was disclosed and still held by the senior/key personnel (as defined in this policy)

ii. BHSF has determined that the SFI is related to a PHS-Funded Research project

iii. BHSF has determined that the SFI constitutes a FCOI

c. Written requests for SFIs of Investigators will be channeled to Research Compliance for processing. The information will include

i. the Investigator's name,

ii. the Investigator's title and role with respect to the research project,

iii. the identity of the entity in which the SFI is held,

iv. the nature of the SFI, and

v. the approximate dollar value of the SFI, or a statement that the financial interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

d. Written responses will be sent to the requestor within five (5) business days of a request.

e. The above information made available shall consist of the minimum elements as required by 45 CFR Part 50, Subpart F and shall be provided by written response to the requestor upon consultation with legal counsel on whether there are any legal or contractual obligations of confidentiality that would prevent or limit the information that can be disclosed and in compliance with:

a. BHSF-301, Release of News to the Media

b. BHSF-850, Appropriate Routing of Requests for Information and Notifications of Billing Discrepancies by Federally Funded Programs.

7. **Records Retention:**

Records pertaining to individual financial conflict of interest in research vetting and management including, but not limited to, Research Financial Disclosure Forms and management plans will be retained in accordance with policy BHSF-451.01, Records Retention but for not less than three (3) years from the date of the final expenditure report submitted to the funding PHS-component.

SUPPORTING/REFERENCE DOCUMENTATION:

- 21 CFR 54, Financial Disclosures by Clinical Investigators
- 42 CFR 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought ("FCOI Regulations")
- 45 CFR 94, Responsible Prospective Contractor

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:

- BHSF-301, Release of News to the Media
- BHSF-451.01, Records Retention
- BHSF-454, Physician Conflict of Interest Policy – Physician Employees
- BHSF-819, Code of Ethics
- BHSF-827, Employee Conflict of Interest
- BHSF-834.03, Financial Conflict of Interest
- BHSF-850, Appropriate Routing of Requests for Information and Notifications of Billing Discrepancies by Federally Funded Programs
- BHSF-823, Compliance Hotline

Attachment:

- Research Financial Disclosure Form (RFDF)

ENFORCEMENT & SANCTIONS:

Enforcement of this policy will be performed by Baptist Health South Florida's Privacy Office, Information Technology's Security Team, and the Conflicts of Interest in Research Committee.