

BSA HEALTH SYSTEM
PROCEDURE

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 1

Authorized by:

John J. Montville

Name

Director

Title

[Signature]

Signature

04-13-2015

Date

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 2

PURPOSE

- 1.1 To define the process that the Principal Investigator (PI), Sub-Investigator (SI) and HCC should take in notifying the Sponsor and the IRB of any financial conflicts of interest relating to their participation in clinical research at HCC.
- 1.2 To comply with applicable regulations.

RESPONSIBILITIES

- 2.1 The PI and Sub-I are responsible for ensuring that the Sponsor, IRB and HCC receive accurate and up-to-date financial information, as described herein.

PROCEDURES

- 3.1 The current content of this policy should be made available to the public on the HCC website.

Industry Sponsored Studies Under FDA Regulations.

- 3.2 For studies sponsored by pharmaceutical and device manufacturers that are performed pursuant to FDA regulations, the PI and any Sub-I should complete and submit accurate and complete financial disclosure forms, as requested by the Sponsor, including information for the PI or the Sub-I and his or her immediate family (note that this information may be disclosed to CMS or other federal agencies by the Sponsor).
 - 3.2.1 The PI and Sub-I should submit updates to the Sponsor, as necessary, to ensure the Sponsor possesses accurate information with respect to financial interests held by the PI, the Sub-I or the PI's or Sub-I's immediate family.
 - 3.2.2 The PI and any Sub-I should submit to the IRB, at a minimum, the same financial disclosure information submitted to the Sponsor, as well as other financial information requested by the IRB, so that the IRB can consider what financial disclosures are appropriate to include in the informed consent form, if any.
 - 3.2.3 The PI and Sub-I should submit updates to the IRB, as necessary, to ensure the IRB possesses accurate information with respect to financial interests held by the PI, the Sub-I or the PI's or Sub-I's immediate family.

PHS Funded Research

- 3.3 **Investigator Disclosure to HCC.** At the time of application for PHS sponsored research, Investigators are required to complete Attachment A: Financial Conflict of Interest Disclosure Form to disclose all Reviewable Interests (namely, (i) any Significant Financial Interests (SFIs) belonging to the Investigator or the Investigator's Family, and (ii) any Travel, to the extent the Investigator determines that the Reviewable

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 3

Interest relates to the Investigators' Institutional Responsibilities) received in the preceding twelve (12) months.

3.3.1 As used below and in the attached forms, the following terms shall be defined as follows (unless otherwise defined herein, capitalized terms shall have the same meaning as in 42 CFR § 50.603):

3.3.1.1 **Designated Official.** The official who receives Investigator's reports of Significant Financial Interests and reviews these reports to determine whether the interest is related to is related to the PHS sponsored research. The current Designated Official will be the HCC Director.

3.3.1.2 **Financial Conflict of Interest (FCOI).** A Significant Financial Interest or Travel that could directly and significantly affect the design, conduct, or reporting of PHS sponsored research.

3.3.1.3 **FCOI Management Plan:** A plan that shall specify the actions that have been, and shall be, taken to manage FCOIs. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

See Attachment B for example FCOI Management Plan.

3.3.1.4 **Institutional Responsibilities.** An Investigator's professional responsibilities on behalf of HCC (e.g., research, research consultation, and professional practice).

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 4

- 3.3.1.5 **Investigator.** The PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS sponsored research at HCC.
- 3.3.1.6 **Reviewable Interest.** Any Significant Financial Interest (SFI) belonging to an Investigator or an Investigator's spouse and dependent children, and any Travel, to the extent either relates to the Investigators' Institutional Responsibilities.
- 3.3.1.7 **Senior/Key Personnel.** Senior/key personnel means the Investigator and any other person identified as senior/key personnel by HCC in the grant application, progress report, or any other report submitted to PHS by HCC.
- 3.3.1.8 **Significant Financial Interest (SFI).** A financial interest consisting of one or more of the following interests that appears to be related to the Investigator's institutional responsibilities:
- With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measure of fair market value) in the entity as of the date of the disclosure exceeds \$5,000.
 - With respect to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or
 - Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
 - *Exclusions:* The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by HCC to Investigator if the Investigator is currently employed or otherwise appointed by HCC, including intellectual property rights assigned to HCC and agreements to share in royalties related to such rights; 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 or higher

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 5

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.

3.3.1.9 **Travel.** Any travel that is reimbursed (*i.e.*, the Investigator is made whole for the financial outlay required) or sponsored (*i.e.*, the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) other than by HCC, 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.

3.3.2 Investigators must update their disclosures of Reviewable Interest annually during the period of the PHS award, as well as within thirty (30) days of discovering or acquiring a new Reviewable Interest.

3.3.2.1 *Travel Disclosures:* Only PHS-funded Investigators are required to disclose Travel. The following information must be provided in connection with any Travel disclosure provided in the context of PHS-sponsored research:

- The purpose of the trip;
- The identity of the Sponsor/organizer of the trip;
- The destination of the trip; and
- The duration of the trip.

3.4 **Review by HCC.** Prior to expenditure of any funds under a PHS sponsored research award, the Designated Official must reasonably determine whether any Reviewable Interest disclosed by any Investigator is: 1) related to the Sponsored Research; and 2) whether the Reviewable Interest constitutes a Financial Conflict of Interest (FCOI). If an FCOI is determined to exist, the Designated Official must determine how the FCOI will be managed.

3.4.1 *Relatedness Standard:* An Investigator's Reviewable Interest is related to PHS sponsored research when the Designated Official determines that the PHS sponsored research could be affected by the Reviewable Interest; or is in an entity whose financial interest could be affected by the Sponsored Research.

3.4.2 *FCOI Standard:* An FCOI exists if the Designated Official determines that the Reviewable Interest related to the Sponsored Research could directly and

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 6

significantly affect the design, conduct or reporting of the PHS sponsored research.

3.5 Management of Identified FCOIs.

3.5.1 *Management Techniques:* For any identified FCOI, HCC, through its Designated Official, will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the Research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable FCOI Management Plan to manage such conflicts.

3.5.1.1 Investigators have an on-going obligation to adhere to the FCOI Management Plan and failure to do so may be grounds for sanctions under this policy.

3.5.1.2 HCC will monitor Investigator compliance with an imposed FCOI Management Plan on an ongoing basis until the completion of the PHS sponsored research project.

3.6 Reporting FCOIs to PHS.

3.6.1 *Content of Report:* For all PHS awards, prior to expenditure of any funds under the award, HCC is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report. In cases in which HCC identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the HCC shall not submit an FCOI report to PHS.

3.6.2 *Timing of Report:* HCC is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI (as described in Section 3.8).

3.6.3 *Annual FCOI Reports:* For any FCOI previously reported by HCC with regard to an ongoing PHS sponsored research project, HCC shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the FCOI Management Plan for the duration of the PHS sponsored research. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. HCC 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.

3.7 **Public Accessibility.** For PHS sponsored research, HCC will ensure public accessibility of the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until HCC establishes a mechanism of making such information available through a publicly accessible website, HCC will, upon receipt of a complete written request for information, provide a written response within five (5) business days regarding any SFI

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 7

disclosed and still held by the Senior/Key Personnel that has been determined to relate to the PHS sponsored research and constitute an FCOI pursuant to this policy.

- 3.7.1 The FCOI information that HCC makes public will include the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) 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.
- 3.7.2 If HCC uses a web site to make the FCOI information available to the public, the information that the HCC posts shall be updated at least annually. The web site shall note that the information provided is current as of the date listed and subject to updates, on at least an annual basis and within 60 days of HCC's identification of a new FCOI.
- 3.7.3 If HCC responds to written requests for the purposes of this subsection, HCC will note in its written response that the information provided is current as of the date of the correspondence 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 requested subsequently by the requestor.
- 3.7.4 HCC shall maintain information concerning the SFI, for responses to written requests or for posting via HCC's publicly accessible web site for at least three years from the date that the information was most recently updated.
- 3.8 **New Interests that Arise During an On-Going Sponsored Research Project.** To the extent a new Reviewable Interest is disclosed to HCC in the course of an on-going Sponsored Research project (i.e., an Investigator who is new to participating in the Research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), or HCC identifies a Reviewable Interest that was not previously reviewed in a timely manner by HCC in accordance with this policy, HCC will, within 60 days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the Investigator's Research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a FCOI Management Plan in accordance with this policy.
- 3.9 **Retrospective Review, Identification of Bias and Mitigation Reporting.** For PHS-sponsored research, in the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely a Reviewable Interest that is determined to constitute an FCOI; HCC's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, HCC will:

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 8

- 3.9.1 Within 60 days of identifying the SFI: HCC shall implement on at least an interim basis, a FCOI Management Plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest;
- 3.9.2 *Retrospective Review:* HCC shall, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS sponsored research projects to determine whether any PHS-sponsored research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. HCC shall document the retrospective review, which shall include, at a minimum, the following key elements:
- Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has a financial conflict of interest;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - Findings of the review; and
 - Conclusions of the review.
- 3.9.3 *Mitigation:* If bias is found during the retrospective review of PHS-sponsored research, HCC will notify the PHS awarding agency promptly, if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and HCC's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.
- 3.9.3.1 The Designated Official shall determine based on the facts and circumstances of the retrospective review, whether or not to report the Investigator's conduct to the AIO or other appropriate official as potential misconduct as described further in the HCC Scientific Misconduct, Prevention, Detection, Reporting & Investigation policy.

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 9

3.9.4 *Disclosure for PHS-Sponsored Drug or device Research:* In any case in which the Department of Health and Human Services (HHS) determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by HCC, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

3.10 **Training.** For PHS-sponsored research, Investigators must complete all required conflicts of interest training prior to engaging in Research at or under the auspices of HCC, and at least every four years following the initial training. This training shall include the information contained in this policy, the applicable regulations and the Investigator's responsibilities regarding disclosure and management of FCOIs. Additionally, Investigators will be required to receive training immediately in any of the following circumstances:

- HCC revises its policy or procedures governing FCOI in PHS sponsored research in any manner that affects the requirements applicable to Investigators;
- An Investigator is new to HCC;
- HCC finds that an Investigator is not in compliance with this policy or an imposed management plan.

3.11 **Record Retention.** HCC will maintain records relating to all Investigator disclosures of financial interests, and its review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions taken pursuant to this policy or any retrospective review, for a minimum of three (3) years from the date the final expenditures report is submitted to the PHS.

RELATED SOPs AND OTHER DOCUMENTS

GEN-16: Scientific Misconduct, Prevention, Detection, Reporting & Investigation

ATTACHMENTS

Attachment A: FCOI Disclosure Form

Attachment B: FCOI Management Plan

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN-17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 10

REVISION HISTORY

SOP Revision #	Page (s)	Description of change(s)	Superseded Document

Attachment A
FCOI DISCLOSURE FORM

Financial Disclosure for PHS-Funded Research (Financial Interests Related to Institutional Responsibilities)

1. Any person who is responsible for the design, conduct, or reporting of a Public Health Service (PHS)-funded research project must submit the PHS Financial Disclosure at the time of proposal submission.
2. BSA Research staff may contact Investigators who have disclosed any Significant Financial Interests (SFI) to request additional information.
3. The Conflict of Interest (COI) Designated Official will review this Form to determine whether or not the disclosed SFI is related to the research project.
4. The Designated Official will consider whether the Investigator's SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research project. Please allow sufficient time for the Designated Official's review.
5. Submission of PHS Financial Disclosure is required (i) on an annual basis for non-competing continuation awards, (ii) when a new Investigator is added to the project, or (iii) when an Investigator's financial interests increase, whichever comes first. It is also required when an Investigator transfers PHS-funded research to BSA.

Who is considered an "Investigator," and therefore required to disclose? "Investigator" means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding.

What is an entity? Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

What is a "Significant Financial Interest"? A significant 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, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measure of fair market value) in the entity as of the date of the disclosure exceeds \$5,000;
2. With regard to any non-publicly traded entity, any remuneration received from entity in 12 months preceding disclosure, when aggregated, exceeds \$5,000; or when Investigator holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest). Exclude income from seminars, lectures, or teaching engagements sponsored by a U.S. 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;
3. Intellectual property rights and interests held by the Investigator, or Investigator's spouse, or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than BSA upon receipt of income related to such rights and interests in 12 months preceding disclosure.
4. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of Investigator and not reimbursed to Investigator) in excess of \$5,000 per entity in the 12 months prior to disclosure, related to Institutional Responsibilities. Excludes travel reimbursed or sponsored by a U.S. Federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(A), an academic teaching hospital, a medical center, or a research institute affiliated with Institution of higher education.

What is not a "Significant Financial Interest"? Significant financial interests do not include (1) payments made by HCC/BSA (salary, royalties, honoraria, expense reimbursement or any other remuneration) or (2) income from seminars, lectures, or teaching engagements sponsored by a U.S. 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 (3) an investment by a mutual fund, pension fund or other investment fund over which the Investigator or his/her immediate family member does not exercise management of fund investment.

What are "Institutional Responsibilities"? "Institutional Responsibilities" are defined as an Investigator's professional responsibilities on behalf of HCC (e.g., research, research consultation, and professional practice).

Who is the Designated Official? The official who receives Investigator's reports of Significant Financial Interests and reviews these reports to determine whether the interest is related to is related to the PHS sponsored research. The current Designated Official will be the HCC Director.

Records

The information provided herein may be released or transmitted to the sponsor, including Federal agency representatives, and as otherwise permitted by law.

BSA HEALTH SYSTEM
PROCEDURE

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN - 17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 12

**Financial Disclosure for PHS-Funded Research (Financial Interests
Related to Institutional Responsibilities)**

In accordance with the BSA Health System, Inc. ("BSA") Policy and Procedure on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Public Health Services Sponsored Awards for Research (42 C.F. Part 50, Subpart F and 45 C.F.R., Part 94), the Principal Investigator and all other BSA personnel must disclose their personal Significant Financial Interests (and those of their spouse and/or dependent children) related to their Institutional Responsibilities. This includes the Principal Investigator, Sub-Investigators, Senior/Key Personnel, and any other individual who is responsible for the design, conduct, or reporting of research funded by PHS or an agency or organization that follows PHS disclosure requirements (for example, American Heart Association, American Cancer Society, etc.). Additional instructions and definitions are on the first page.

Project Information	
Principal Investigator:	Department: Harrington Cancer Center
	Project Start Date:
Project Title:	
Source of funding: <input type="checkbox"/> PHS <input type="checkbox"/> Other (e.g., American Heart Association, American Cancer Society): _____	
<input type="checkbox"/> Subcontract of PHS Funds from _____	
Position of Disclosing Individual	
<input type="checkbox"/> Principal Investigator	<input type="checkbox"/> Research Staff
<input type="checkbox"/> Sub-Investigator	<input type="checkbox"/> Other: _____
Significant Financial Interest Disclosure	

1. Publicly Traded Entity

Income and Equity Interests

In the past 12 months, have you, your spouse, and/or dependent children either:

- (a) received income or payment for services (e.g., consulting fees, honoraria, paid authorship) or
- (b) owned any equity interest (e.g., stock, stock option, or other ownership interest)

from/in any publicly traded entity related to your Institutional Responsibilities exceeding \$5,000 when aggregated (aggregation must occur both across individuals (i.e., you, your spouse, and/or dependent children) and across (a) and (b) listed above)?

Do not include any:

- (a) salary, ownership interest in HCC, or other remuneration paid to you by HCC if you are currently employed or otherwise appointed by HCC;
- (b) income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- (c) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (d) or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

Yes No

2. Non-Publicly Traded Entity

Income

In the past 12 months, have you, your spouse, and/or dependent children received income or other payment for services (e.g., consulting fees, honoraria, paid authorship), exceeding \$5,000, when aggregated, from any non-publicly traded entity related to you Institutional Responsibilities?

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN - 17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 13

Do not include any:

- (a) salary, ownership interest in HCC, or other remuneration paid to you by HCC if you are currently employed or otherwise appointed by HCC;
- (b) income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- (c) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (d) or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

Yes No

Equity Interests

In the past 12 months, have you, your spouse, and/or dependent children owned or acquired any equity interest in any non-publicly traded entity related to your Institutional Responsibilities? This can include any stock, stock option or other ownership interest.

Yes No

3. Disclosure of Public/Non-Public Entity Income and/or Interest

If you answered "Yes" to 1 or 2 above, please complete this question. If, "No" please continue with question 4.

Entity Name	Disclosure Type (Check all that apply.)	Explain how the Disclosed Interest and/or income relates to your "Institutional Responsibilities"
<input type="checkbox"/> Publicly Traded <input type="checkbox"/> Non-Publicly Traded For new Significant Financial Interests, did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: \$ _____ <input type="checkbox"/> Stock <input type="checkbox"/> Stock Options <input type="checkbox"/> Other Ownership Interest Estimated Current Stock/Ownership Interest Value:\$ % Ownership: <input type="checkbox"/> <5% <input type="checkbox"/> 6-10% <input type="checkbox"/> 11-25% <input type="checkbox"/> >26%	Explanation/Additional Comments:
<input type="checkbox"/> Publicly Traded <input type="checkbox"/> Non-Publicly Traded For new Significant Financial Interests, did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: \$ _____ <input type="checkbox"/> Stock <input type="checkbox"/> Stock Options <input type="checkbox"/> Other Ownership Interest Estimated Current Stock/Ownership Interest Value:\$ % Ownership: <input type="checkbox"/> <5% <input type="checkbox"/> 6-10% <input type="checkbox"/> 11-25% <input type="checkbox"/> >26%	Explanation/Additional Comments:

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN - 17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 14

Entity Name	Disclosure Type (Check all that apply.)	Explain how the Disclosed Interest and/or income relates to your "Institutional Responsibilities"
<input type="checkbox"/> Publicly Traded <input type="checkbox"/> Non-Publicly Traded For new Significant Financial Interests, did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: \$ _____ <input type="checkbox"/> Stock <input type="checkbox"/> Stock Options <input type="checkbox"/> Other Ownership Interest _____	Explanation/Additional Comments
	Estimated Current Stock/Ownership Interest Value:\$ _____ % Ownership: <input type="checkbox"/> <5% <input type="checkbox"/> 6-10% <input type="checkbox"/> 11-25% <input type="checkbox"/> >26%	

Attach additional sheets as necessary.

4. Intellectual Property Rights and Interests

In the past 12 months, have you, your spouse, and/or dependent children received any intellectual property rights or interests (e.g. patents, copyrights, royalties from such rights, and agreements to share in royalties related to intellectual property rights) related to your Institutional Responsibilities? **Do not include** (1) any intellectual property rights of interests owned by HCC/BSA if you are currently employed or otherwise appointed by HCC/BSA; (2) unlicensed intellectual property that does not generate income.

Yes No

5. Disclosure of Intellectual Property Rights and Interests

If you answered "Yes" to 4 above, please complete this question. If, "No" please continue with question 6.

Entity Name	Disclosure Type (Check all that apply.)	Explain how the Disclosed Interest and/or income relates to your "Institutional Responsibilities"
For new Significant Financial Interests, did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Approximate Value: \$ _____ Description of Intellectual Property Right/Interest	Explanation/Additional Comments:
	Description of Intellectual Property Right/Interest	
For new Significant Financial Interests, did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Approximate Value: \$ _____ Description of Intellectual Property Right/Interest	Explanation/Additional Comments:
	Description of Intellectual Property Right/Interest	

Attach additional sheets as necessary.

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN - 17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 15

6. Travel Reimbursement/Sponsorship

In the last 12 months, have you received travel reimbursement or been sponsored for travel (i.e. travel expenses paid on your behalf) in excess of \$5,000 per entity (i.e., cumulative across the entity if multiple trips occurred), by any entity related to your Institutional Responsibilities? This **does not include** travel sponsored or reimbursed by a U.S. federal, state, or local government agency, a U.S. institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.

Yes No

7. Disclosure of Reimbursement or Sponsored Travel

If you answered "Yes" to 6 above, please complete this question. If, "No" please continue with question 8.

Past Travel (last 12 months)

Entity	Destination	Duration	Purpose of Trip	Value of Trip

Planned Travel (upcoming 12 months)

Entity	Destination	Duration	Purpose of Trip	Value of Trip
	<input type="checkbox"/> Continental U.S. <input type="checkbox"/> Other	<input type="checkbox"/> 1-5 Days <input type="checkbox"/> 6-10 Days <input type="checkbox"/> Over 10 Days		
	<input type="checkbox"/> Continental U.S. <input type="checkbox"/> Other	<input type="checkbox"/> 1-5 Days <input type="checkbox"/> 6-10 Days <input type="checkbox"/> Over 10 Days		
	<input type="checkbox"/> Continental U.S. <input type="checkbox"/> Other	<input type="checkbox"/> 1-5 Days <input type="checkbox"/> 6-10 Days <input type="checkbox"/> Over 10 Days		
	<input type="checkbox"/> Continental U.S. <input type="checkbox"/> Other	<input type="checkbox"/> 1-5 Days <input type="checkbox"/> 6-10 Days <input type="checkbox"/> Over 10 Days		
	<input type="checkbox"/> Continental U.S. <input type="checkbox"/> Other	<input type="checkbox"/> 1-5 Days <input type="checkbox"/> 6-10 Days <input type="checkbox"/> Over 10 Days		

Attach additional sheets as necessary.

8. Acknowledgment and Certification

I certify that this is a complete disclosure of all my Significant Financial Interests related to my Institutional Responsibilities and I have used all reasonable diligence in preparing this Financial Interest Disclosure, and to the best of my knowledge it is true and complete. I also acknowledge that by signing my name below that it is my responsibility to disclose, within 30 days, any new significant financial interests obtained during the term of the above proposed project.

Signature: _____ Date: _____

Printed Name: _____

The information provided herein may be released or transmitted to the sponsor, including federal agency representatives, and as otherwise permitted by law.

Attach additional sheets as required to identify and include all financial disclosure information.

**BSA HEALTH SYSTEM
PROCEDURE**

DEPARTMENT: HARRINGTON CANCER CENTER RESEARCH	PROCEDURE: Financial Conflict of Interests
SOP No.: GEN - 17	EFFECTIVE DATE: APRIL 15, 2015
VERSION No.: 01	PAGE: 16

Attachment B

FCOI MANAGEMENT PLAN

For the PHS sponsored research project listed below, HCC has reviewed the Significant Financial Disclosure Form of the Identified Investigator. HCC has determined that the significant financial interest relates to PHS-funded research and may constitute a financial conflict of interest (FCOI). Below is the management plan designed to safeguard objectivity and includes specific actions that have been taken to manage this FCOI.

Name of Investigator:	Title: <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Other:	
Project Number:	Funding Agency:	Project Start Date:
Project Title:		
Project Scope/Abstract:		
Role and Principal Duties of the Investigator:		
Management Plan Details:		
Name of Independent Monitor (if appropriate):		
Investigator's Telephone Number:	Investigator's Email:	
Investigator Confirmation I confirm that I have been consulted during the development of this FCOI management plan and agree to abide by its conditions or restrictions.		
_____ Signature	_____ Date	