

Policy Name:	Conflicts of Interest in Research
Policy Number:	None
Department:	BSMH Office of Research
Functional Area:	Clinical Research
Contributing Department:	BSMH Compliance, BSMH Legal
Approved by:	Chief Compliance Officer
Effective Date:	06/21/2022
Version:	2.0
Status:	Approved
Manual	Research
Section	BSMH System-wide Research Policies

I. Mission, Vision and Values

This organization aims to ensure its Mission, vision, and values are reflected in all organizational-wide policies, procedures and guidelines. This policy reflects our values of acting with integrity and exercising good stewardship ensuring Financial Conflicts of Interests related to BSMH research activities are identified, evaluated and managed to reduce the risk of bias and be made free of any considerations unrelated to the best interests of the organization.

II. Policy

A conflict of interest (COI) can be any situation in which financial or other personal considerations have the potential to compromise a researcher's professional judgment and objectivity in the design, conduct or reporting of research. To avoid or mitigate real or perceived financial COIs, all Bon Secours Mercy Health ("BSMH") employees and others acting on its behalf engaged in the design, conduct or reporting of research must comply with BSMH requirements regarding the disclosure, review and reporting of COIs in research and with the financial conflict of interest ("COI") requirements as defined by federal regulations governing Promoting Objectivity in Research, 42 CFR Part 50 Subpart P; 21 CFR Part 54; 45 CFR Part 94.

It is the policy of Bon Secours Mercy Health (BSMH) to ensure that all BSMH employees engaged in the design, conduct, or reporting of research comply with financial conflict of interest ("COI") requirements as defined by federal regulations governing Promoting Objectivity in Research, 42 CFR Part 50 Subpart P; 21 CFR Part 54; 45 CFR Part 94.

III. Purpose

The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest ("FCOI") related to BSMH research activities so that BSMH may reduce the risk of bias resulting from Investigator financial conflict of interest.

IV. Scope

This is a system-wide policy that applies to all BSMH employees and others acting on its behalf engaged in the design, conduct or reporting of research.

This policy applies to Investigators, broadly defined as any individual engaged in the design, conduct, or reporting of research.

V. Policy Details

A. Investigator's Duty to Disclose Significant Financial Interests ("SFI")

1. All Investigators are required to disclose their outside SFIs to BSMH at the time of submission of a proposed research study. Investigators that do not have a SFI to report are still required to complete the disclosure form.

- B. Assessment of Disclosure
 - 1. If the disclosure form reveals a SFI, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a FCOI. If a FCOI exists, the Institutional Official will take action to manage the FCOI, including the reduction or elimination of the conflict, as appropriate.
- C. Determination and Management of FCOI
 - 1. If a FCOI is determined to exist, a management plan will be provided to the Investigator containing conditions or restrictions regarding participation in the conduct of research including, but not limited to, the following:
 - a) Public disclosure of FCOI (e.g., when presenting or publishing the research);
 - b) Monitoring of research by independent reviewers;
 - c) Modification of the planned activities (possibly subject to sponsor approval);
 - d) Disqualification from participation in all or part of the project;
 - e) Divestiture of SFI;
 - f) Severance of relationship(s) creating conflict;
 - g) Disclosure of FCOI directly to research subjects, if relevant.
- D. Investigator's Obligation to Complete Training and General Obligation to Cooperate
 - 1. All Investigators must complete training on this Policy, and fully understanding their responsibilities regarding disclosure of SFIs.
 - 2. Principal Investigators share responsibility with the BSMH Office of Research and BSMH Compliance for ensuring compliance with this Policy on their research projects.

VI. Definitions

Clinical Trial means a research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Clinical Trial Intellectual Property means an Investigator's interest in intellectual property that is the subject of copyright, issued patent, or a patent application (regardless of whether the intellectual property has a been patented, licensed, or assigned to BSMH) if such intellectual property is being tested, evaluated, or developed in, or if its commercial value could be affected by the Clinical Trial in which the Investigator is engaged or proposes to engage.¹

Conflict of Interest Committee (COI Committee) means BSMH's committee or individuals (BSMH Chief Compliance Officer and BSMH Legal) that advise the Institutional Official responsible for financial conflict of interest matters.

Covered Party means an Investigator, project director, research staff that are designated by the Investigator or project director to conduct Research activities, any person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, including collaborators or consultants.

¹ Engaging in a trial includes, but is not limited to, serving as a Principal Investigator, Co-Investigator, regulatory sponsor/holder of an investigation drug application with the FDA or investigational device exemption granted by the FDA, or in any other role responsible for the design, conduct, or reporting of the trial (including reporting results to the FDA); performing any other subject-related activity specific to the trial, such as the recruitment, selection, or enrollment of subjects, obtaining informed consent, providing subject treatment and care specific to the trial, or performing study procedures; or collecting, analyzing or interpreting data.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.²

Fiduciary Role means membership on the governing board of an entity, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or limited liability company member with management responsibilities.

Financial Conflict of Interest ("FCOI") means a Significant Financial Interest, and for PHS Investigators, includes Sponsored Travel, that BSMH reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family Member, whether or not the value is readily ascertainable. *Financial Interest* does NOT include:

1. Salary, royalties, or other remuneration from BSMH;
2. Income from the authorship of academic or scholarly works;
3. Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
4. Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Institutional Official means the individual within BSMH who is ultimately responsible for the review of disclosures of SFI and the management of Financial Conflicts of Interest in Research. For the purposes of this Policy, the Institutional Official is designated as the Vice President Clinical Research.

Institutional Responsibilities means the Investigator's professional responsibilities associated with his or her Institutional employment, such as clinical activities, administration, research, teaching, and internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of research, or proposals for research funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include assistants, coordinators, nurses, scientists, or students. The definition may also include collaborators or consultants, as appropriate.

² While "Family" is not explicitly defined in the regulations, a SFI includes financial interest of the Investigator's spouse and dependent children.

Public Health Service ("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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality ("AHRQ"), Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention ("CDC"), Federal Occupational Health, Food and Drug Administration ("FDA"), Health Resources and Services Administration, Indian Health Service, National Institutes of Health ("NIH"), and Substance Abuse and Mental Health Services Administration.

PHS-Funded Research means Research for which funding is available from a PHS awarding component through a grant.

Remuneration includes salary and payments for services, such as consulting fees, honoraria or paid authorship, and cash or in-kind gifts from entities for which you provide services and, for PHS Investigators, Sponsored Travel.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

Significant Financial Interest ("SFI") means one or more of the following of the Investigator or the Investigator's Family that reasonably appear to be related to the Investigator's Institutional responsibilities:

1. With regard to:
 - a) A publicly traded entity: An SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b) A non-publicly traded entity: A SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or if the Investigator or Family Member holds any equity interest;
2. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
3. Clinical trial intellectual property rights (and royalties or other remuneration, if any, paid with respect to such rights);
4. Any Fiduciary role in an entity.

Significant Financial Interest does NOT include:

1. Remuneration from BSMH; (including salary and royalty payments); and
2. Remuneration paid to an Investigator's Family by any entity that would not reasonably appear to be related to the Investigator's Institutional Responsibilities; and
3. Remuneration from authorship of academic or scholarly works, regardless of the source; and
4. Remuneration from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education; U.S. research institutions affiliated with U.S. institutions of higher education, U.S. academic teaching hospitals, and U.S. medical centers; and
5. Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles.

Sponsored Travel (applies only to PHS Investigators) means:

1. Travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period, and
2. Travel reimbursed to or paid on behalf of an Investigator's Family by a single entity in any 12-month period ONLY if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities.

VII. Attachments

- A - Procedure
- B - Guiding Principles
- C - Disclosure Form

VIII. Related Policies

- BSMH Compliance Potential Conflict of Interest Policy
- BSMH Vendor Relations and Gifts Policy
- BMSH Allowed Outside Activities Policy
- BSMH Nepotism and Employment Conflicts of Interest
- BSMH Business Ethics, Gifts, and Gratuities Guidelines

IX. Regulatory Notices

Nothing in this policy modifies the at-will status of any organizational associate or otherwise creates a contractual relationship between the organization and any associate.

The organization in its sole discretion, reserves the right to amend, terminate or discontinue this policy at any time, with or without advance notice.

X. Version Control

Version	Approved Date	Next Review Date	Description	Supersedes, if applicable	Prepared By
1.0	6/21/2022	6/21/2024	Policy created and approved	BSMH Policy and Procedures on Conflicts of Interest in Research; any Mercy Health Research COI Policies	Chief Compliance Officer
2.0	1/15/2025	6/21/2024	Moved to new policy template	1.0	Chief Compliance Officer

This policy/procedure/guideline is not intended to establish a standard of clinical or non-clinical care or practice. Rather, this policy/procedure/guideline creates a general tool to help guide decision-making with the understanding that different action(s) may be necessary in response to the totality of the circumstances presented.

Sites revised 01/21/2024 - Bon Secours Mercy Health adopts the above policy, procedure, policy & procedure, guideline, manual / reference guide / instructions, or principle / standard / guidance document for all Bon Secours Mercy Health entities including, but not limited to, facilities doing business as Mercy Health – St. Vincent Medical Center, St. Vincent – St. Charles Hospital, St. Vincent – St. Anne Hospital, Mercy Health – Perrysburg Medical Center, Mercy Health – Tiffin Hospital, Mercy Health – Willard Hospital, Mercy Health – Defiance Hospital, Mercy Health Allen Hospital LLC, Mercy Health - Lorain Hospital, Mercy Health St. Elizabeth Youngstown Hospital, Mercy Health St. Joseph Warren Hospital, Mercy Health - St. Elizabeth Boardman Hospital, Mercy Health - St. Rita's Medical Center, Mercy Health – Springfield Regional Medical Center, Mercy Health - Urbana Hospital, Mercy Health - Anderson Hospital, Mercy Health - Clermont Hospital, Mercy Health – Fairfield Hospital, Mercy Health - West Hospital, The Jewish Hospital – Mercy Health, Mercy Health – Kings Mills Hospital, LLC, Mercy Health - Lourdes Hospital LLC, Mercy Health – Marcum and Wallace Hospital, Chesapeake Hospital Corporation DBA Rappahannock General, Maryview Hospital, Bon Secours Richmond Community, Bon Secours Memorial Regional Medical Center, Bon Secours – St. Mary's Hospital, Bon Secours St. Francis Health System, Bon Secours St. Francis Medical Center, Bon Secours Mary Immaculate Hospital, Bon Secours - Southside Medical Center, Bon Secours Mercy Health Franklin, LLC, and Southern Virginia Medical Center. This also may apply to Bon Secours Mercy Health Medical Group LLC and its medical group affiliates.

Attachment A: Procedure**DISCLOSURE OF FINANCIAL INTERESTS****SFI in Research Disclosure Form**

All investigators must complete a SFI in Research Disclosure Form as follows:

1. At the time of proposal submission;
2. Annually, even if there has been no change since the original disclosure;
3. When added as an Investigator to an ongoing project;
4. Prior to participation in any PHS-funded research;
5. Updated within 30 days in the event of a new SFI or change in previously reported SFI.

The SFI in Research Disclosure Form captures the Investigator's SFI which includes those of him/herself, his/her spouse, and dependent children. The Principal Investigator is responsible for ensuring that all Investigators or sub-investigators involved in the study for which the Investigator is the lead, comply with this policy disclosure requirements.

All Investigators are required to complete the SFI in Research Disclosure Form, even if they have no financial interests to report. Disclosures will be made to the BSMH Office of Research. Investigators are required to personally complete the disclosure form and sign it. This responsibility may not be delegated and the individual making the disclosure must sign his/her form. Either electronically or wet signatures will be accepted.

Investigators conducting clinical trials for the U.S. Food and Drug Administration ("FDA") applications for a human drug, biological product or device must also comply with the FDA requirements that require financial disclosure to be updated both during the course of the study and for one year following the completion of the study.

The SFI in Research Disclosure Form will be submitted to and maintained by the BSMH Office of Research.

Review of SFI in Research Disclosure Forms and Decision

1. The SFI in Research Disclosure Form will be reviewed by the Institutional Official, or designee, and a determination of the existence of a SFI will be made.
2. If an SFI is identified, the Disclosure Form will be reviewed promptly to determine whether an Investigator's disclosed SFI could directly and significantly affect the design, conduct or reporting the research, and would therefore constitute a FCOI.
3. The Institutional Official, or designee, may convene a COI Committee for advisory purposes.
4. At the direction of the Institutional Official, or designee, the Investigator may be included in making the determination and may request additional clarifying information from the Investigator which will be treated in a confidential manner to the extent allowed by law.

If a FCOI exists, the Institutional Official will take action to manage the FCOI including the reduction or elimination of the conflict, as appropriate.

A FCOI will exist when the Institutional Official, or designee, determines that a SFI could directly and significantly affect the design, conduct, or reporting of research. If the Institutional Official determines that there is a FCOI that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any research goes forward.

The Institutional Official, or designee, will periodically review and monitor compliance with the management plan.

Management of Financial Conflict of Interest

If a FCOI is identified for an Investigator conducting research, the Institutional Official, or designee, may request that the Investigator submit a proposed conflict management plan that will detail steps that could be taken to manage, reduce, or eliminate the FCOI. The Institutional Official will review the proposed conflict management plan and approve it or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated to ensure that the design, conduct or reporting of research is free from bias or the appearance of bias. A draft of the management plan will be provided to the Investigator for review and comment before it is finalized. Conditions or restrictions may include, but are not limited to, the following:

1. Public disclosure of FCOI (e.g., when presenting or publishing the research);
2. Monitoring of research by independent reviewers;
3. Modification of the planned activities (possibly subject to sponsor approval);
4. Disqualification from participation in all or part of the project;
5. Divestiture, including reduction or gradual elimination, of SFI;
6. Severance of relationship(s) creating conflict.
7. For research involving human subjects, disclosure of FCOI directly to research subjects.

If BSMH identifies a SFI that was not disclosed or reviewed in a timely manner, it will be reviewed within 60 days from the date the SFI was identified to determine if the SFI is actually a FCOI. An interim management plan will be implemented when necessary.

This policy applies to all types of research conducted at BSMH; however, special precautions must be taken to protect human subjects who participate in research. If a FCOI is identified for an Investigator, the Investigator will need to provide a compelling justification for his/her participation in the research. Compelling justification includes factors such as unique Investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level or risk to human subjects, and the degree to which the financial interest and research are linked. The FCOI and the compelling justification will be reviewed by the Institutional Official or designee, to determine if a management plan is appropriate, or if the Investigator will be prevented from participating in the research. BSMH Legal counsel will be consulted, as needed.

Research will not begin until the appropriate management plan or actions have been taken by the Investigator to mitigate or eliminate the FCOI, and any other necessary actions, such as IRB approval or the clinical trial contract has been fully executed.

Appeals

Investigators may appeal an Institutional Official's decision in writing within 15 days of receipt of management plan or other decision related to FCOI. The written appeal should be directed to the Institutional Official and should include details regarding the Investigator's concern and/or compelling circumstances which support the request for a proposed revision to that decision. The Institutional Official, or designee, will make a final determination. Final appeal determinations will be reported to the IRB.

Compliance

1. As part of the SFI in Research Disclosure Form, each Investigator must certify that if BSMH determines a FCOI exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.
2. Investigator compliance with management plans will be monitored by Institutional Official, or designee. The frequency of monitoring will be dictated by sponsor/agency requirements and management plan provisions.
3. An independent review of the monitoring activities will be undertaken annually by BSMH Compliance.
4. As part of the BSMH Conflict of Interest policy annual audit program, BSMH Compliance will undertake a review of a sample of COI disclosures related to research activities and audit against the CMS Open Payments database to confirm disclosures have been made in accordance with this policy and the BSMH COI policy.

Records

1. BSMH Office of Research will maintain records of all disclosures and associated activities securely and confidentially.
2. Records will be maintained for three (3) years following the termination or completion of a study, submission of the final expenditures report, or the date of final resolutions of any investigation, audit, or similar action involving the records.

Enforcement

1. Failure to comply with this policy to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by BSMH will be considered a deviation from accepted standards of conducting research at BSMH.
2. The Institutional Official will investigate alleged violations of this policy and will make recommendations for action to the BSMH CCO. Breaches of policy include, but are not limited to: failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed by BSMH.
3. Failure to comply with this policy may result in disciplinary actions and/or sanctions, including but not limited to, formal reprimand; a letter to the Investigator's file; non-renewal/termination of the Investigator's ability to conduct clinical trials. Reporting to sponsor(s) and the Department of Health and Human Services will be filed as required.
4. **Disciplinary Action**
In the event of an Investigator's failure to comply with this Policy, the Institutional Official, in consultation with the BSMH Chief Clinical Officer, serving as the Local Market Research Accountable Executive ("RAE"), may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator, and where applicable, the Institutional Review Board ("IRB"), and will notify the individual of the right to appeal the decision. The Institutional Official will be informed so that he/she may inform the Local Market RAE.

Retrospective Review

In addition, if the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, a committee appointed by the Institutional Official, chaired by the Chief Compliance Officer, or designee, will complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include, but not be limited to, the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, BSMH may be required to make such information available to the PHS Awarding Component and/or DHHS, to a requestor of information concerning FCOI related to PHS funding or to the primary entity who made the funding available to BSMH. If BSMH is required or requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

PHS Funded Research Addendum

This PHS Funded Research Addendum implements the requirements of certain federal regulations, specifically 42 CFR 50 and 45 CFR 94, and applies to all projects funded directly or indirectly through a subaward from another organization, by the PHS other than SBIR or STTR. This PHS Addendum supplements BSMH's Policy on Conflicts of Interest in Research. PHS regulations differ, in some respects, from BSMH's Policy. It is imperative that every BSMH Investigator that accepts PHS funding, whether directly or indirectly, becomes

familiar with, and abides by, the provisions of this PHS Addendum. Note: some foundations that fund research elect to apply PHS standards and requirements relating to financial conflicts of interests.

PHS Funded Research. The following additional requirements apply to all research funded by the PHS and any PHS Awarding Component including the National Institutes of Health (NIH).

Reporting

1. BSMH will provide the PHS Awarding Component a FCOI report as outlined in the regulations:
 - a) Initial Reports During an Ongoing NIH-Funded Study - Prior to expenditure of any funds under a NIH-funded project, BSMH will provide to the NIH a FCOI report regarding any Investigator SFI found by BSMH to be a FCOI. BSMH will also provide a FCOI report whenever an Investigator does not timely disclose a SFI or whenever BSMH, for whatever reason, does not review a disclosed SFI and BSMH then determines that a FCOI exists.
 - i. BSMH will provide a FCOI report within 60 days after its determination that a FCOI exists for an Investigator who is newly participating in the study, for an existing Investigator who discloses a new SFI, or when BSMH identifies a FCOI not previously disclosed.
 - ii. Whenever an Investigator does not disclose timely a previously existing SFI or BSMH fails to review a previously existing SFI during an ongoing NIH-funded project, BSMH's designated official(s) will, within 60 days: review the SFI; determine whether it is related to the NIH-funded research; determine whether a FCOI exists. If so, BSMH will implement, on at least an interim basis, a management plan that will specify the actions that have been, or will be, taken to manage the FCOI going forward and submit a FCOI report to the NIH.
 - iii. In addition to the FCOI report, BSMH will, within 120 days of its determination of non-compliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research.
 - iv. Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
 - v. If bias is found, BSMH will notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and BSMH's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter, BSMH will submit FCOI reports annually.
 - b) If FCOI reports required above, BSMH will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of BSMH's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:
 - i. Grant/contract/project number
 - ii. PD/PI
 - iii. Name of Investigator with FCOI
 - iv. Name of entity with which the Investigator has a FCOI
 - v. Nature of the FCOI (e.g. equity, consulting fees, travel reimbursement or honoraria)
 - vi. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
 - vii. Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
 - viii. Description of the key elements of the management plan

- c) For any FCOI previously reported by BSMH, BSMH will provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI must be submitted to the NIH for the duration of the project period.

Reporting to PHS

The Institutional Official will report FCOI or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

Travel - PHS funded Investigators 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 his/her Institutional Responsibilities and that are not reimbursed or 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.

The disclosure requirement also applies to the Investigator's spouse and dependent children. The travel disclosure must include at least the following:

1. Purpose of the trip
2. Identity of the sponsor/organizer Destination
3. Duration of trip
4. Monetary value, if known.

Travel disclosure will be reviewed by Institutional Official to determine whether additional information is needed in order to determine whether the travel constitutes an FCOI with the PHS- funded research. Disclosure of travel must occur no more than 30 days after the last day of the trip.

Travel Disclosure

Investigators funded by PHS must also disclose reimbursed or sponsored travel (i.e., travel which is paid on behalf of the Investigator rather than reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Institutional Responsibilities, during the previous 12 months. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial COI with the Investigator's research.

Public Accessibility

1. This policy will be posted on BSMH's publicly accessible website. In addition, BSMH will ensure public accessibility by a written response to any requestor within 5 business days of receipt of a request by the Institutional Official for information concerning any SFI disclosed to BSMH that meets the following criteria:
 - a) The SFI was disclosed and is still held by the Institutional Official as defined by this policy;
 - b) BSMH determines that the SFI is related to PHS-funded research; and
 - c) BSMH determines that the SFI is a FCOI
2. The information that BSMH will make available via a written response to any requestor within 5 business days of receipt of a request will include at least the following:
 - a) Investigator's name;
 - b) Investigator's title and role with respect to the research study/project;
 - c) Name of the entity in which the SFI is held;
 - d) Nature of the SFI;
 - e) Approximate dollar value of the SFI using dollar ranges 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;

- f) 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 BSMH's identification of a new FCOI, which should be requested subsequently by the requestor.
3. This information will remain available for 3 years from the date the information was most recently updated.

Financial Conflict of Interest Training Requirements

1. Each Investigator must complete training prior to engaging in NIH-funded research and at least every 4 years, and as soon as reasonably possible under the following circumstances:
 - a) BSMH's FCOI policy changes in a manner that affect Investigator requirements;
 - b) An Investigator is new to BSMH;
 - c) BSMH finds that an Investigator is not in compliance with BSMH's FCOI policy or management plan.

Training

Each Investigator must complete training on this Policy, fully understanding the Investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to the institution, or if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities.

Record Retention

The BSMH Office of Research will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

Attachment B: Guiding Principles

A number of guiding principles inform our approach to identifying and addressing Financial Conflicts of Interest. These include:

1. An Investigator's first and primary responsibility is to support and advance BSMH's mission, rather than to advance his or her personal financial interests.
2. Research must be undertaken to advance patient care and new knowledge and not an Investigator's or the Investigator's Family's personal financial interest.
3. Financial Conflicts of Interest must be identified and either managed or eliminated.
4. Disclosure of Significant Financial Interests and Outside Professional Activities is integral to identification of Financial Conflicts of Interest.
5. An Investigator must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the Investigator's or the Investigator's Family's financial interests.
6. Research results must not be withheld or provided on a preferential basis for the benefit of an Investigator's or the Investigator's Family's financial interest.
7. BSMH's resources, names and trademarks may not be used for personal benefit.
8. Investigators must disclose any actual Financial Conflicts of Interests and any Significant Financial Interests that may appear to give rise to a Financial Conflict of Interest to staff who participate in their research.
9. Extra scrutiny must be given to potential Financial Conflicts of Interest in research involving human subjects.
10. An Investigator may not supervise directly or indirectly any member of his or her Family nor may an Investigator assume the role of advocate or judge regarding a Family member's employment, salary, or promotion.

Attachment C: COI in Research Disclosure Form (Contact BSMH Office of Research)