Financial Interests in Research Manual

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Interim revision dates are noted on individual procedures.

See Policy and Procedure/Form Creation or Revision to request changes to this document.

Financial Interests in Research Manual

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Financial Interests in Research Policy

Date of Last Revision/Review: 08/24/12

Background

It is essential that all research activities be conducted free from any conflict of interest or the appearance of a conflict. In order to protect the objectivity of individuals who are engaged in these activities, and to preserve the integrity of the College, all must strive to avoid any apparent or actual conflict of interest and must respond appropriately when conflicts arise.

This Policy is designed to maintain the trust of the public, research volunteers, and the scientific and medical community in the College's mission and to maintain compliance with applicable laws and regulations.

These standards are designed so that there is no reasonable expectation of bias in research based on its:

- Design
- Conduct
- Reporting

Federal regulations on FCOI reference specifically:

- Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for PHS grants or cooperative agreements (Revised 2011)
- Title 45 CFR Part 94 for PHS research contracts (Revised 2011)
- National Science Foundation (NSF) Chapter IV – Grantee Standards, Section A Conflict of Interest Policies
- FDA Regulations at 21 CFR Part 54
- Accreditation Standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP):
  - Standard I.6.A. - Institutional Financial Conflicts of Interest (pg. 40)
  - Standard I.6.B. - Investigators holding a Financial Interest (pgs. 41-42)

Exceptions: These regulations do not apply to applications for funding for:

- Phase I Small Business Innovation Research (SBIR)
- Phase I Small Business Technology Transfer (STTR)

Applicability

Institutions and Investigators must comply with this policy.

Investigators Holding a Financial Interest in Research

Date of Last Revision/Review: 08/24/12

General requirements

All Investigators are required to report to BCM and Significant Financial Interests (SFIs) that reasonably appear to be related to the investigator's Institutional Responsibilities.

BCM must review the matter and determine:

- If an Investigator's Significant Financial Interest is related to the research, and
- If the research-related Significant Financial Interest is a Financial Conflict of Interest that should be managed, reduced or eliminated.

Research with human subjects

Special precautions must be taken to avoid perceived or actual bias with respect to research involving human subjects that encompasses the evaluation of strategies or products that may affect or be affected by the financial interests of BCM or BCM Investigators.

A BCM Investigator shall not ordinarily participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly affect the design, conduct or reporting of the Research unless he/she presents a compelling justification for a waiver of this policy based on his/her unique qualifications as an Investigator.

The degree of risk to human subjects and the compelling justification will be reviewed by the Research Conflict of Interest Committee (RCOIC). If compelling circumstances are found, the Research will be subject to stringent management measures to ensure the safety of the human participants and the integrity of the Research.

The IRB must review and approve any management plan for human subject Research. The IRB may require additional safeguards to protect human subject participants in addition to those required by the RCOIC.

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Investigators Holding a Financial Interest in Research, Continued

Reporting requirements and process	The definitions in this policy describe Financial Interests and Significant Financial Interests related to Institutional Responsibilities. Individuals may have difficulty deciding if an interest is related to their Institutional Responsibilities. **Accordingly, individuals should always err on the side of reporting any Significant Financial Interest that they think may be related to their Institutional Responsibilities; especially any interests that may affect, or be affected by, the research on which they are working.** Once any Significant Financial Interest is reported, **and before the research project will be funded**, BCM will: • Confirm whether the Significant Financial Interest **related to their institutional responsibilities** is related to research; and if so, • Determine whether the interest constitutes a Financial Conflict of Interest that must be managed, reduced or eliminated. **Individuals should not make the decision about whether a Significant Financial Interest Related to Research is a Financial Conflict of Interest; this determination must only be made through the review process of the RCOIC.**
Training requirements and process	Prior to engaging in research related to PHS funding or human research, Investigators must complete training in the Collaborative Institutional Training Initiative (CITI) program (for instructions see, FAQs: RCOI On-line Training) and must ensure that training is conducted at least every 4 years. BCM FCOI training must also be performed when BCM announces and posts changes to its FCOI submission policy, when such changes affect Investigator submissions of Significant Financial Interests.

Investigator Responsibilities

Date of Last Revision/Review: 03/12/21

Duties of investigators

The Investigator is responsible for:

- Providing a list of his/her known Significant Financial Interests (SFIs) reasonably related to his/her Institutional Responsibilities (and those of his/her spouse and dependent children), and denoting for the BCM RCOIC:
- SFIs that would reasonably appear to be affected by the research, and
- SFIs in entities whose financial interests would reasonably appear to be affected by the research
- Disclosing reimbursed or sponsored travel that has occurred as an SFI within the preceding 12 months of the initial submission in the Disclosure of Outside Interests Tool which includes, at a minimum, for the trip its:
- Purpose
- Sponsor/organizer/vendor paying on behalf of or reimbursing the investigator
- Destination
- Duration
- ***Note*:** Go to Disclosure of Outside Interests Tool > Do you want to submit – Financial disclosure for outside interests > B. Meals, Entertainment or Sponsored Travel and disclose the above required items and an estimated value for the trip is required.
- Updating all SFIs either on an annual basis or within 30 days of discovering or acquiring a new SFI that would reasonably appear to be related to the Investigator's Institutional Responsibilities and denoting the details of these interests
- Requesting that the RCOI office review all Investigators' Significant Financial Interest disclosure forms when the Principal Investigator of the project has been notified that the research project will receive funding
- Ensuring that BCM FCOI training has been completed prior to engaging in research, every four years thereafter, and as BCM announces changes requiring additional training completion
- Abiding by the guidance and instructions of the Research Conflict of Interest Committee's management plan for any determined Financial Conflict of Interest
- Investigators with joint (dual) appointments at Baylor College of Medicine (BCM) and the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) who receive or apply for NIH funding and/or NIH support for research must have a valid Memorandum of Understanding (MOU) between the two institutions. See also Joint Appointments with the Veterans Administration in the Sponsored Programs manual.

For more information on the process of submitting an electFor more information on the process of submitting an electronic Significant Financial Interest disclosure form see, SFI Submission Process

Investigator Responsibilities, Continued

Disclosure

Submitting the eSP2 Proposal - At the time that a research proposal is submitted in the online proposal routing system, eSP2 in BRAIN:

- The Principal Investigator/designated Administrative Contact will identify all investigators and whether each is considered BCM or non-BCM personnel in BRAIN eSP2 (Proposal Entry – Personnel).
- The Principal Investigator/designated Administrative Contact will create Significant Financial Interest forms in BRAIN eSP2 (Proposal Entry – Certify/Submit) for Investigators that have entered Significant Financial Interests and Sponsored or Reimbursed Travel in the Disclosure of Outside Interests Tool.
- Non-BCM investigators whose institution is not listed on the Federal Demonstration Partnership (FDP) Institutional Clearinghouse – A Subrecipient/Collaborator form for each investigator attached to the Principal Investigator's electronic Significant Financial Interest disclosure form
- Non-BCM investigator whose institution is listed on the Federal Demonstration Partnership (FDP) Institutional Clearinghouse – No form is needed for these investigators

***Note*:** Any identified FCOI will require a specific assurance from the subrecipient institution that any such FCOI has been reduced, managed, or eliminated. See Institutional reporting of FCOI.

Funding the Proposal – At the time that a research proposal is ready to be funded in the online proposal routing system, the BCM SPO will assure that the required disclosures have been reviewed and approved by the Research Conflict of Interest Office and/or the Research Conflict of Interest Committee.

Please see the Research Conflict of Interest Office website, Process for new, competing and resubmitted applications.

Institutional Financial Interest – Human Research

Date of Last Revision/Review: 08/24/12

Financial interest overview

BCM has an obligation to protect the rights and welfare of participants, ensure the integrity of the research, and to ensure the credibility of the human research protection program.

The College and its leadership may have financial interests that conflict with these obligations. For example, human research may be conducted by BCM personnel while:

- BCM has an active management role in the company which is funding the research (agreements through BCM Technologies with outside companies may place BCM in such a role)
- The research involves an investigational product for which, if used, BCM is entitled to receive royalties or milestone payments
- An Institutional Leader engages in the review or oversight of College decision-making about a particular research activity while having a Significant Financial Interest in the sponsor or funding source for the research. This includes decisions about allocating College resources to projects or activities where the decision maker may be influenced by the potential for personal financial gain.

Gifts

Gifts to the College with the intent of funding a research project are treated as a Research Award by the BCM Research Sponsored Programs. Please see the BCM Sponsored Programs Handbook for Investigators, "Types of Awards – Donations/Gifts" for further information.

Other Gifts to the College are managed as Investments of BCM assets as above. BCM segregates human subject research and investment management functions by ensuring that its investments are managed externally.

Responsibilities for Institutional Financial Interests

Date of Last Revision/Review: 08/24/12

Institutional leaders

Each Institutional Leader is responsible for:

- Annually disclosing to the College, his/her Significant Financial Interests (and those of his/her spouse and dependent children)
- Updating all financial disclosures as new Significant Financial Interests are obtained

The RCOIC determines those personnel meeting the definition of Institutional Leader.

Research Conflict of Interest office

The Research Conflict of Interest office is responsible for assuring that:

- Institutional leader disclosure statements are submitted annually
- The online protocol routing system, BRAIN, is updated appropriately to capture Institutional Conflicts of Interest (ICOI) of the College and its institutional leaders
- Reports of Institutional Conflict of Interest in Human Subject Research are appropriately routed to the RCOIC for review
- The RCOIC reviews the disclosure statement and formulates a management plan for Significant Financial Interests in an investigational product or in a sponsor of human subject research. Examples of management strategies that may be recommended by the RCOIC include (but are not limited to):
  - Recusal of an Institutional Official from certain deliberations
  - Relegation of oversight of a multi-center trial to another institution
  - Monitoring by an oversight body with external members (e.g., a data and safety monitoring board)
  - External IRB review of the research
  - Disclosure of the institutional COI in informed consent forms, public presentations and publications
  - Disclosure of the institutional COI to other centers in a multi-center trial
  - Divestiture of the interest
- The IRB is apprised of the determinations of the RCOIC

IRB responsibilities

The IRB must review and approve any ICOI management plan for human subject research. The IRB may require additional safeguards to protect human subject participants in addition to those required by the RCOIC.

The IRB communicates its final determinations to the:

- Individual with the ICOI and his or her supervisor
- RCOIC

Identification and Management of ICOI

Date of Last Revision/Review: 08/24/12

Overview

When an Institutional Conflict of Interest is identified, the RCOIC and the IRB must be informed to review and make a determination of the appropriate actions to be taken.

- The Office of Research receives reports of institutional interests from the Baylor Licensing Group (BLG) and BCM Technologies (BCMT) through BRAIN
- Institutional leaders disclose their significant financial interests at least annually
- When an investigator selects as a funding source one of the businesses in which BCM or its Institutional Leader has a financial interest, the investigator is notified through BRAIN of the institutional relationship, and that the protocol requires additional review by the Research Conflict of Interest Committee (RCOIC)
- The RCOIC reviews the Institutional Conflict of Interest and proposes a plan to manage the conflict as it relates to the proposed research, so that it does not adversely affect participant protections. The plan is forwarded to the IRB.
- The IRB reviews the plan recommended by the RCOIC and may impose additional requirements (including, but not limited to, the appointment of an independent DSMB, information about the interest being included in the consent form, or moving the research to another site) to protect human subjects and to ensure the objectivity of the research
- The convened IRB has the final authority to decide whether the financial interest and its management, if any, allows the research to be approved

The BCM Research Compliance Services monitors approved management plans on a regular basis to ensure compliance. Reports of findings are made to the IRB and the RCOIC for review and deliberation.

Record Requirements

Date of Last Revision/Review: 12/03/15

Record requirements

This topic discusses record retention requirements for significant financial interest disclosures.

Item	Description
Document flow procedures	The Research Conflict of Interest office is responsible for developing and implementing procedures for efficient document flow.
Records defined	Records must include all information required under Department of Health and Human Services (DHHS) regulations: • Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought 42 CFR Part 50 Subpart F, grants • Responsible Prospective Contractors, 45 CFR Part 94, contracts
Findings and determinations	Records include documentation of all findings and determinations.
File organization	Files are organized such that the following information may be readily accessed: • Written operating procedures • Forms submitted by Investigator listing Significant Financial Interests • Institutional financial interests • Documentation of Research Conflict of Interest Committee determinations • Correspondence between Research Conflict of Interest Committee, the IRB, and investigators • Any required periodic reports by Investigator with FCOI
Record retention	Records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest are kept for at least three years from: • The date of submission of the final expenditures report on the PHS funded research, or • Where applicable, from other dates specified in 45 CFR 75.361 for different situations

Research Conflict of Interest Committee (RCOIC)

Date of Last Revision/Review: 01/03/20

Introduction

The RCOIC is a standing committee of the College. This topic discusses the membership of the RCOIC, terms and duties.

Charge

The primary charge of the committee is:

For Investigator Financial Interests in Research

- Review individual electronic Significant Financial Interest Disclosure Forms and related documents for those who have disclosed a significant financial interest related to Institutional Responsibilities which were determined to be related to research
- Evaluate Significant Financial Interests related to research and determine if such interests related to research constitute a Financial Conflict of Interest (FCOI)
- If a financial conflict of interest exists, develop appropriate safeguards and management plans to ensure that the disclosing person's financial interest will not bias the design, conduct or reporting of the research project
- Review any concerns that an investigator may have failed to comply with the FCOI policy, see Handling Non-Compliance Concerns

For Institutional Financial Interests in Human Research

- Review documents related to the financial interests of the College in proposed human research
- Establish those personnel meeting the definition of Senior Administrators for the purposes of this manual
- Determine whether or not an Institutional Research Financial Conflict of Interest exists
- If a financial conflict of interest exists, develop appropriate safeguards and/or management plans to ensure that the Institution's financial interest will not affect the rights and welfare of participants, the integrity of the research, or the credibility of the human research protection program

The secondary charge of the committee is to:

- Implement, oversee and enforce the conflict of interest in research provisions of the BCM Research Conflict of Interest policies
- Recommend to the Signatory Official provisions as needed to accomplish the objectives of the policy and the requirements of the federal regulations
- Monitor the management of identified conflicts of interest in research during the conduct of the research

Scope of review

The RCOIC reviews significant financial interest disclosure forms and reviews the documentation related to any identified Financial Conflicts of Interest of investigators and Institutional Conflicts of Interest.

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Research Conflict of Interest Committee (RCOIC), Continued

Committee appointment	The RCOIC is a standing committee of the College. Members of standing committees are appointed for one year terms. Any member's term may be extended for an additional one-year term without limitation. Nominations for membership may come from any of the following: • RCOIC Chairperson • RCOIC Members • Department Chairpersons • RCOIC Administrative staff • Officials of the College or its components
RCOIC support	The Research Conflict of Interest office provides the administrative support to the Research Conflict of Interest Committee and provides SFIs of the Investigator to the RCOIC for review. The Research Conflict of Interest office communicates the determinations of the committee to the: • Investigator • Principal investigator (to alert that another investigator engaged in the research has an FCOI) • Sponsored Programs Office • IRB office • Institutional Official
Membership	Alternate members are encouraged to attend RCOIC meetings and participate in all other RCOIC activities.
Meeting frequency	**Meetings** Standing meetings shall be scheduled monthly and held as needed. Special meetings may be called by the Chair of the RCOIC, or the RCOI Office, for investigations and other special matters. **Committee Reviews Outside Convened Meetings** A designated member of the RCOIC may review investigators' significant financial interest disclosure forms and make a determination between convened meetings as necessary. The designated member's review and determination will be presented to the fully convened RCOIC at its next meeting. These determinations and management plans if required are to be considered committee decisions.
Quorum	A meeting quorum is reached when a majority of voting members is present: • Each member shall have one vote • Actions of the RCOIC shall require a majority of the votes cast at any meeting in which a quorum is present • Non-RCOIC members do not vote on RCOIC matters.

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Research Conflict of Interest Committee (RCOIC), Continued

Conflict of interest of a committee member	Recusal is required whenever any member has a conflict of interest (personal or due to work-related responsibilities) regarding any matter under review.
Consultants	The RCOI Office may invite individuals outside of the committee to attend meetings to provide specific expertise and insight.
Meeting minutes	Minutes shall be kept of all meetings of the RCOIC and approved at subsequent meetings of the RCOIC. • Meeting minutes serve as records of proceedings • Minutes must be in sufficient detail to show: – Attendance at the meetings – Actions taken by the committee – Basis for determining whether an interest constitutes a Significant Financial Interest – Basis for determining whether a Significant Financial Interest constitutes a Financial Conflict of Interest that must be managed, reduced or eliminated – Basis for developing and approving management plans and/or monitoring plans • Minutes and report materials of the meetings are approved and then filed with the RCOI office. Minutes are made available for review by authorized Baylor personnel, such as but not limited to, the Baylor Institutional Review Board.

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Research Conflict of Interest Committee (RCOIC), Continued

Disclosure review The steps for review, determination and communication for Investigators holding a significant financial interest are as follows:

Step	Action
1	Electronic disclosure forms and supporting documentation will be reviewed by the Research Conflict of Interest (RCOI) Office for the disclosure of a significant financial interest.
2	The RCOI office will review all forms submitted in which a significant financial interest has been identified. The RCOI office will provide the RCOIC with forms in which a significant financial interest has been identified and is related to the research for which funding is sought.
3	After reviewing the financial disclosure, the Research Conflict of Interest Committee must determine whether an FCOI or ICOI exists.
4	If an FCOI or ICOI exists, the committee determines what actions should be taken by the Institution or Investigator to manage, reduce or eliminate such a conflict: • When an FCOI has been identified, the committee may require the investigator to disclose the conflicting interest in any of the following: – Journal article – Abstract – Transcript – Other form of publication – At presentations at scientific meetings – Other forms of public presentation • The committee may require additional management strategies, including elimination of the conflict by divestiture or by restricting the participation of the conflicted party in the research • If the DHHS determines that an Investigator has an FCOI that was not managed or reported by the Institution, the RCOIC will require the Investigator, at a minimum, to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations • In considering Institutional COIs (in human research by definition), the RCOIC will evaluate: – Level of risk to human subjects in the research – Risk to the integrity and objectivity of the research – How direct and immediate the level of authority of the Senior Administrator is (if applicable to the reason for the ICOI) – The risk to the academic freedom and unbiased treatment of the faculty member who has proposed the research – The perceived risk to the credibility of the human research protection program • If ICOI exists, normally either the research may not be carried out by BCM investigators or divestiture will be required • For human research, the IRB must review and approve any management plan for human subject research. The IRB may require additional safeguards to protect human subject participants in addition to those required by the RCOIC.

Institutional Reporting Responsibilities

Date of Last Revision/Review: 07/08/13

Institutional reporting of FCOI

The SPO and Institutional Official use the following process for reporting FCOI:

- For awarded grants and cooperative agreements, all FCOI reports must be submitted through the electronic Research Administration (eRA) Commons
- For awarded contracts, reports should be sent to the appropriate Director, Office of Acquisitions
- The Institution's report should include the following information:
  – Contract/project number
  – Principal Investigator (PI) or contact PI if the grant/contract is awarded under the multiple PI model
  – Name of Investigator (if different from the PI) with the FCOI
  – An indication as to whether the conflict has been managed, reduced, or eliminated

FCOI reporting timeframes

Prior to the Institution's expenditure of any funds under the award the Institution will:

- Report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution for:
  – Identified FCOIs for Investigators newly participating in the project; or
  – Investigators who are already participating in the project
- Report to the PHS awarding component FCOIs annually and for any changes to the management plan
- Assure that the interest has been managed, reduced or eliminated

For any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification. The Institution agrees to make information available, upon request, to the DHHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

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Institutional Reporting Responsibilities, Continued

FCOI reporting timeframes (cont.)

Annual Reporting of FCOI

For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project.

The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution 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.

Public Accessibility of FCOI

The Institution agrees to make FCOI information for Investigators designated as senior/key personnel available within five business days of a written request; such information will include the minimum elements as required by the PHS regulations. FCOI information will remain accessible for three years from the date the information was determined to be a FCOI.

To request information about Financial Conflicts of Interest (FCOIs) for senior/key personnel contact the Research Conflict of Interest office at coi@bcm.edu or (713) 798-6548.

Non-compliance

The Institutional Official must promptly notify the PHS awarding component of the corrective action taken or to be taken upon finding non-compliance with this policy.

The PHS awarding component will review the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions on how to maintain appropriate objectivity in the funded project.

Handling Non-Compliance Concerns

Date of Last Revision/Review: 06/15/21

Non-compliance with FCOI requirements

Concerns that an investigator may have failed to comply with the FCOI policy will be referred to the Research Conflict of Interest Committee for further review.

The Research Conflict of Interest Committee will determine whether:

- An Investigator failed to comply with the Institution's FCOI policy, and
- If this failure has biased any of the following:
  – Design
  – Conduct
  – Reporting of research

Non-Compliance Reporting Requirements

If the Committee determines that both of the above have occurred, it proceeds as follows:

- For a funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research
- Provide any findings to the Institutional Official
- Provide a report to the appropriate PHS awarding component
- If BCM is a subrecipient, provide the primary awarding institution with the RCOIC determination

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Handling Non-Compliance Concerns, Continued

Actions the RCOIC may take

After the Research Conflict of Interest Committee makes a final determination on non-compliance with disclosure requirements or the conditions of a management plan, it may take any reasonable corrective action it deems appropriate. Below are examples of possible actions, but should not be construed as an all-encompassing list:

- Acceptance of the investigator's proposal for correction
- Notification and involvement from other individuals from BCM (i.e. Dean, Department Chair)
- Requiring the Investigator to revisit BCM's policy on Significant Financial Interest disclosures and retake the BCM FCOI training; this retraining is mandatory
- Requiring the Investigator to take additional training in the ethics and regulation of research
- Increased reporting by the Investigator or increased monitoring of the research
- Suspension of the BCM account set up for grant costs
- Disapproval of future grant proposals where the non-compliant investigator is listed as key personnel
- Referral of the issue to other committees responsible for possible further review and action (i.e. the IRB)
- Any other action the Research Conflict of Interest Committee deems appropriate to ensure compliance with federal regulations or BCM policy

The Institutional Official must promptly notify the PHS awarding component of the corrective action taken or to be taken.

Retrospective reviews

Whenever the Institution identifies a significant financial interest that was not timely disclosed by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the RCOIC shall, within sixty days:

- Review the significant financial interest
- Determine whether it is related to PHS-funded research
- Determine whether an FCOI exists. If an FCOI does exist, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

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Handling Non-Compliance Concerns, Continued

Retrospective reviews (cont.)

- Whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the RCOIC to constitute a FCOI; failure by the RCOIC to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Institution shall, within 120 days of the RCOIC determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-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.
- The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of 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
  - Conclusions of the review

Based on the results of the retrospective review, if appropriate, the Institutional Official shall update the previously submitted FCOI report, specifying the actions of the management plan for the FCOI going forward.

If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Management of FCOI

Date of Last Revision/Review: 02/15/18

Routine monitoring for BCM Investigators

Routine monitoring of any FCOI is carried out by Research Compliance Services (RCS) once the RCOIC has determined the existence of a conflicting interest, or as part of an ongoing quality improvement activity.

RCS will monitor Investigator management plans for investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

RCS generates a Monitoring Report which summarizes the Investigator's adherence to the management plan. The Monitoring Report is provided to the RCOIC which determines whether or not the Investigator has been compliant with the management plan. See Handling Non-Compliance Concerns for more information regarding the process the RCOIC uses for making such determinations. The RCOIC determination is provided to the Investigator.

Upon request from the awarding institution the BCM RCOI office provides the following:

- Copy of the BCM FCOI monitoring procedures
- Date of last monitoring date, and
- A letter detailing any findings from the monitoring and determination from the RCOIC

Routine monitoring for non-BCM Investigators

A subrecipient Institution which has a policy compliant with 42 CFR Part 94 and 42 CFR Part 50, has attested at time of proposal that it will report to BCM within 30 days prior to expenditure of funding any FCOI for the Investigator participating in a research project for which BCM is the primary awarding Institution.

Once the BCM RCOI office has been notified of an FCOI for an Investigator at a subrecipient Institution, Research Compliance Services requests the following from the subrecipient Institution:

- Copy of the subrecipient Institutional procedures, and
- The monitoring report which includes the Significant Financial Interests and how the subrecipient Institution determined the interests to be an FCOI

RCS will monitor Investigator management plans for investigator compliance with the management plan in this way on an ongoing basis until the completion of the PHS-funded research project.

For businesses or companies that do not have an FCOI policy compliant with 42 CFR Part 94 and 42 CFR Part 50, routine monitoring is done by Research Compliance Services once the BCM RCOIC has identified a conflicting interest.

Definition of Terms

Date of Last Revision/Review: 12/21/18

Term	Definition
Disclosure	Disclosure (declaration) to the institution of the investigator's financial interests
FDP	Federal Demonstration Partnership (FDP) Institutional Clearinghouse - The Federal Demonstration Partnership (FDP) is an association of federal agencies, academic research institutions with administrative, faculty and technical representation, and research policy organizations that work to streamline the administration of federally sponsored research. The FDP Institutional Clearinghouse is a site that provides a central location for educational institutions and other entities to document that they are in compliance with the PHS Financial Conflict of Interest (FCOI) rules and regulations. This site is expected to be used by PHS recipients to verify the compliance of their potential subrecipients with these regulations.
Financial Conflict of Interest (FCOI)	Exists when the Institutional designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the research in **any** of the following: • Design • Conduct • Reporting
Financial interest	Financial interest means anything of monetary value, whether or not the value is readily ascertainable. For a more expansive definition, please visit BCM's general policy on Conflicts of Interest.
Financial interest related to the research	In human, FDA-regulated research, means financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.
Institutional Conflict of Interest (ICOI)	Occurs in human subject research when financial interests of BCM or of an Institutional Leader acting within his or her authority on behalf of the institution, might affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of human subject research, or the rights and welfare of participants.

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Definition of Terms, Continued

Term	Definition
Institutional leader	An individual with direct responsibility for research and because of his or her position at BCM, or one of our affiliates, has the capacity to reasonably affect or appear to affect the conduct, review, or oversight of current or proposed research at the institution. *Example*: The Institutional Leader may have the authority to make supervisory decisions about College or administrative unit research programs, or faculty. Institutional leaders may include: • President • Vice President • Department Chairs • Institute or Center Directors • Chairs and Vice Chairs of the IRB, COIC & RCOIC

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Definition of Terms, Continued

Term	Definition
Institutional official	The Institutional Official is the person designated by Baylor College of Medicine to oversee the solicitation and review of financial reporting statements from any Investigator who will be participating in Research. For purposes of this Policy, the Institutional Official is the Senior Vice President for Research or designee(s).
Institutional responsibilities	Institutional responsibilities are defined by the 2011 revised PHS regulation as an Investigator's professional responsibilities on behalf of the Institution. BCM defines institutional responsibilities as professional BCM work-related responsibilities which may include research, research consultation, teaching, professional practice, clinical activities, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
Investigator (including investigator's spouse and dependent children)	• **Any person** who is responsible for the design, conduct, or reporting of funded or proposed research. This includes Principal Investigators (PIs always meet the definition), sub-grantees, contractors, collaborators, sub-recipients, and sub-contractors meeting the definition of investigator. • Compliance Guidance – Consider all personnel designing, conducting or reporting research. This may include study coordinators and statisticians, for example. Investigators may include paid and non-paid personnel as well as collaborators from other institutions.
Monitoring report	A report generated by Research Compliance Services for an Investigator who has an FCOI as determined by the RCOIC, such report includes information which details how the Investigator adheres to the management plan. The report is necessary to ensure compliance and that the interests do not bias the design, conduct or reporting of the research.

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Definition of Terms, Continued

Term	Definition
Not a significant financial interest	The following are not considered significant financial interests: salary, royalties, or other remuneration from the Institution. • 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 • Income from service on advisory committees or review panels 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 • Income from investment vehicles, such as mutual funds and retirement accounts, in which the Investigator does not directly control the investment decisions made in these vehicles • Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights • Salary, royalties or other payments that when aggregated for the Investigator (and the Investigator's spouse and dependent children) over the next twelve months are not expected to exceed $5,000
Regulation or FCOI regulation	Regulations (requirements) that apply to both grants and contracts
Report	The Institution’s report (accounting) to the PHS of identified FCOIs

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Definition of Terms, Continued

Term	Definition
Significant Financial Interest (SFI)	A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities: • With regard to any publicly traded entity - a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; • With regard to any non-publicly traded entity - a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or • Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. • Investigators also must disclose the occurrence of any reimbursed or sponsored travel within the preceding 12 months (e.g., 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) at of the time of submission of the research proposal/project and within 30 days of a new occurrence. Investigators must complete the Travel Document, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

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Definition of Terms, Continued

Term	Definition
Sponsored travel	Any reimbursed travel 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 Institutional Responsibilities This does not include travel that is reimbursed or sponsored by: • A US Federal, State, or local government agency (*i.e.*, NIH), • BCM or any US Institution of higher education as defined at 20 U.S.C. 1001(a), or • An academic teaching hospital, a medical center, or a research institute in the US that is affiliated with an Institution of higher education in the US This may include but is not limited to sponsored travel for: • A scientific meeting • An Investigator's meeting • A study committee or other research team meeting • Consulting • Continuing medical education
Subrecipients	For research that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions

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The community of professionals in the area of research objectivity has generously provided their own written policies and procedures and the language of varied policies and procedures has been used throughout this document.