



Policy: *Conflicts of Interest in Research*

Responsible Office: Compliance Office	Category: Governance & Administration
Authorized: Executive Vice President, General Counsel	Policy Number: ADM-C028
Review Frequency: 2 years	Effective: 07/2016

Policy Statement

- I. The Center must ensure scientific objectivity in all Research conducted at the Center.
- II. Investigators, Key Personnel and all other persons at the Center who are responsible for the design, conduct, or reporting of Research must disclose in a Conflict of Interest Disclosure Statement any and all Investigator SFIs or other interests that are, or may be perceived to be, related to the individual's Center Responsibilities. Persons with knowledge of Center financial and strategic relationships must disclose any and all Institutional SFIs that are, or may be perceived to be, related to Research conducted at the Center.
- III. Persons at the Center are obligated to submit or update their Conflict of Interest Disclosure Statement prior to the submission of an application to PHS for Research funding, within thirty (30) days of discovering or acquiring a new Investigator SFI, and on an annual basis.
- IV. If the Conflict Committee finds that a Financial Conflict of Interest exists, the Conflict Committee will devise and approve a Conflict of Interest Management Plan setting forth the requirements for the management, reduction or elimination of the FCOI.
- V. This Plan shall be approved prior to the expenditure of PHS funds for such Research and/or the activation of the project, protocol or grant, including the enrollment of any subjects in Research, as applicable.
- VI. An Investigator with a clinical role in human subjects research may not receive personal payments for services more than \$10,000 during a twelve-month period from an entity that sponsors, funds or otherwise supports human subjects research in which the Investigator participates. Equity interests which are held by an Investigator and fall under the definition of a SFI shall be handled on a case-by-case basis for human subjects research. An Investigator with a nonclinical role in human subjects research (who has received personal payments for services more than \$10,000 during a twelve-month period) must have a Conflict of Interest Management Plan in place. (The above payments from the entity shall not include reasonable reimbursement for travel.)
- VII. An Investigator may not receive personal payments for services more than \$10,000 during a twelve-month period from an entity that sponsors, funds or otherwise supports non-human subjects research in which the Investigator participates unless a Conflict of Interest Management Plan has been implemented to manage such conflict(s) of interest. Equity interests which are held by an Investigator and fall under the definition of a SFI shall be handled on a case-by-case basis for non-human subjects research. (The above payments from the entity shall not include reasonable reimbursement for travel.)
- VIII. In the absence of a FCOI, if an Investigator receives personal payments for services ranging from \$5,001 to \$10,000 during a twelve-month period from a company that sponsors, funds or otherwise supports either human or non-human subjects research in which the Investigator participates, the Conflict Committee will approve an AFI Memorandum setting forth certain disclosure requirements related to the SFI(s), (The above payments from the entity shall not include reasonable reimbursement for travel.)
- IX. Investigators may direct questions related to this Policy, any SFI, or any FCOI to the Designated



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Official, the Compliance Office or the Chair(s) of the Conflict Committee.

- X. The Compliance Office will maintain complete records relating to any SFI and FCOI, including records of SFIs and FCOIs reviewed by the Conflict Committee, for at least three (3) years following the submission date of the final expenditure report or for the appropriate retention period if no final expenditure report is submitted.
- XI. The Center will provide training to inform each Investigator of this Policy, of the Investigator's responsibilities regarding disclosure of SFIs, and of the federal regulations relevant to disclosure of FCOIs and SFIs.
- XII. The Center shall make its records related to an Investigator SFI or FCOI available to the United States Department of Health and Human Services, including PHS or other sponsors, as applicable.
- XIII. Prior to the Center's expenditure of any PHS funds for Research, the Center shall make available the Key Personnel Significant Financial Interest Information to the public by responding to a request within five (5) business days, if the Investigator SFI meets the following three criteria:
 - a. The Investigator SFI is held by a Key Personnel for PHS-funded Research;
 - b. The Center determines that the Investigator SFI is related to the PHS-funded Research; and
 - c. The Center determines that the Investigator SFI is an FCOI.

The Center will disclose in its written response that the information provided is current as of the date of the correspondence and is subject to updates that will only be provided upon a subsequent request. New FCOIs will be publically available within sixty (60) days of identification. The written request for Key Personnel Significant Financial Information meeting the above criteria shall be addressed and mailed to the following:

Moffitt Cancer Center Compliance Office
Attention: Conflict of Interest Program
12902 Magnolia Avenue
Tampa, Florida 33612

The response to the request will be sent within five (5) business days from the Compliance Office's receipt of the request. Further, requests for updates to previously requested information must be submitted to the Center as described above. Such records will be maintained as required by law.

Information concerning the SFIs of the Key Personnel shall remain available for response to written requests for at least three years from the date that the information was most recently updated.

- XIV. The Center will coordinate and communicate its FCOI findings with the appropriate regulatory bodies, such as the Institutional Review Board.
 - XV. If the Center carries out Research through Subrecipients, the Center shall take reasonable steps to ensure that investigators working for such entities comply with this Policy or shall require such entities certify to the Center that they have a conflict of interest policy that complies with applicable federal regulations. The agreement between the Center and the Subrecipient will include the following:
 - a. Clear delineation as to whether this Policy of the Center (prime recipient) or the Subrecipient's conflict of interest policy will apply; and
 - b. The time period in which the Subrecipient must disclose its SFIs or FCOIs, as relevant, to the Center.
 - XVI. This Policy will be applied prospectively to each PHS-funded project with an issue date of the Notice of Award (including noncompeting continuations) that is on or subsequent to the effective
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date of this Policy.

Purpose

The purpose of this Policy is to promote objectivity in Research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of Research will be biased or compromised by any conflicting financial interest of an Investigator or the Center. This Policy will also ensure that all Research carried out at the Center is performed with the utmost concern for patient safety and scientific integrity. Though not all financial interests of those conducting Research are impermissible, it is necessary to ensure that conflicts between the Investigator's professional obligations and private interests are effectively managed, reduced or eliminated for Research conducted at the Center.

The best way to address FCOIs is through reliance on complete, timely disclosure of SFIs that may give rise to the appearance of impropriety, and the effective management of FCOIs through case-by-case examinations by a committee dedicated to resolving FCOIs.

Scope

This Policy applies to certain faculty and staff, Center management (director level and above), M2Gen staff, and clinical faculty and advanced practice professionals.

Stakeholders: Clinical Investigations, Research Administration, Office of Innovation and Industry Alliances , Office of Sponsored Research, Office of Grant and Contract Accounting, Office of Protocol Review.

Procedures

A. Disclosure of SFIs

1. Individual SFIs
 - a. Investigators, Key Personnel, and Center Officials shall complete and submit a Conflict of Interest Disclosure Statement describing all Investigator SFIs and other interests as required through the on-line system ("COI Database") or directly to the Designated Official or the Compliance Office.
 - b. Each individual's Conflict of Interest Disclosure Statement must be made prior to the submission of an application to PHS for research funding, and updated at least annually and within thirty (30) days of discovering or acquiring a new SFI. New Investigators and Key Personnel must complete the Conflict of Interest Disclosure Statement within sixty (60) days of employment by the Center.
 - c. Any misrepresentation, falsification, or omission on the Conflict of Interest Disclosure Statement by an Investigator may lead to immediate removal of the Investigator from the Research study and/or all future studies, or other disciplinary action.
 - d. If the Center or an Investigator misrepresents, falsifies, or omits information concerning an Investigator SFI, or does not report or manage such information in compliance with the federal regulations, the Investigator may be required to disclose the FCOI in every public presentation of the applicable study and provide an addendum to previously published results. In any case in which the U.S. Department of Health & Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness
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of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by the Institution as required by this regulation, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

2. Institutional SFIs
 - a. When the Center holds a direct or indirect SFI, either as primary site or non-primary site for Research, it is presumed that the Center shall not conduct Research until such FCOIs have been managed, reduced or eliminated.
 - b. The Center will identify individuals within each corporate entity who shall promptly disclose Institutional SFIs to the Compliance Office by completing and submitting a Conflict of Interest Disclosure Statement.

B. Identification of AFIs

1. The Compliance Office shall review each SFI and determine if the Investigator participates in any Research sponsored, funded, or otherwise supported by the entity in which the SFI exists. If the SFI is related and not determined to be an FCOI, but warrants certain measures to reduce the potential for bias resulting from the SFI, the Compliance Office shall prepare an AFI Memorandum.
2. The AFI Memorandum shall be approved by the Conflict Committee or designee.

C. Identification and Initial Review of Potential FCOIs

1. The Office of Sponsored Research will review each PHS grant submission to ensure that all Investigators have submitted a Conflict of Interest Disclosure Statement within the past twelve (12) months.
2. Prior to activation of a PHS grant award, the SFIs of all Investigators participating on the project will be reviewed by the Designated Official, Office of Sponsored Research, and/or the Compliance Office to determine if the SFI is related to the Research and may constitute an FCOI. To assess whether an SFI is related to PHS-funded Research, it must be reasonably determined that the SFI could be affected by the PHS-funded Research or is in an entity whose financial interest could be affected by the Research.
3. If the Designated Official and the Compliance Office find that there is an SFI that constitutes an FCOI, or if a potential FCOI exists, the Compliance Office will notify the Principal Investigator and the conflicted Investigator(s) involved in the Research that a potential FCOI exists and that the Research shall not be approved until it is determined that a potential FCOI does not exist or the FCOI has been managed, reduced or eliminated.
4. If an SFI arises for an Investigator participating in ongoing Research, the Investigator shall submit an updated Conflict of Interest Disclosure Statement within thirty (30) days.
5. The Compliance Office shall notify the Conflict Committee when a potential FCOI is disclosed or otherwise is brought to the attention of the Designated Official or the Compliance Office.

D. Conflict Committee Review of Actual and Potential FCOIs

1. The Conflict Committee shall review all potential FCOIs it becomes aware of to determine if an actual FCOI exists. For PHS funded research, the Conflict Committee shall determine if an actual FCOI exists prior to the expenditure of PHS funds.
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2. To determine whether an FCOI exists for an Investigator, the Conflict Committee shall examine each of the Investigator SFIs disclosed by the Investigator. In determining whether the disclosed SFI creates an FCOI, the Conflict Committee shall consider the nature and amount of each SFI disclosed, the totality of all the disclosed SFIs, and the effect on any PHS-funded Research.
 3. If the Conflict Committee finds that an FCOI exists, the Conflict Committee shall inform the Investigator of the existence of the FCOI and may allow the Investigator to further explain the FCOI and provide input on how to manage, reduce or eliminate the FCOI.
 4. To manage, reduce or eliminate an FCOI, the Conflict Committee should look at the totality of the circumstances surrounding the disclosure pertaining to the Investigator and the Center, the particular FCOI, and the Research. As Research and particular FCOIs are unique, the Conflict Committee shall make an individualized, case-by-case determination of how to best manage, reduce or eliminate the FCOI. Factors for the Conflict Committee to consider in determining which action is appropriate for management of the FCOI may include, but are not limited to:
 - a. All local, State, and Federal Regulations that mandate disclosure and management of FCOIs;
 - b. Whether the individual with the FCOI is the Principal Investigator;
 - c. The degree of influence the Investigator has over the design, conduct, analysis, reporting, or supporting of Research;
 - d. Whether human subjects are or will be involved in the Research;
 - e. Whether compensation is affected by the Research outcome;
 - f. The nature and amount of the SFIs held by the Investigator or Center, taken both individually and as a whole;
 - g. The unique expertise of the Investigator in the area of Research;
 - h. Potential media exposure;
 - i. The consequences of divestiture (e.g., is divestiture possible);
 - j. The ability to adequately protect the integrity of the data and the human subjects; and
 - k. The potential physical harm to human subjects.
 5. To manage, reduce or eliminate an FCOI, the Conflict Committee may require, but is not limited to requiring, any of the following actions:
 - a. Prevention of the Research or action from going forward;
 - b. Public disclosure of the FCOI;
 - c. Disclosure of the FCOI to study subjects on informed consent forms;
 - d. Disqualification of the Investigator or other Key Personnel from participation in the study, or in some part of the data analysis;
 - e. Monitoring of the Investigator and/or the Research by impartial observers capable of taking measures to protect the design, conduct or reporting of the Research against bias from the FCOI;
 - f. Modification of the Research or project;
 - g. Divestiture or minimization of the SFI by the Investigator or Center back to the entity
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- providing the SFI;
- h. Severance of the relationship that created the actual or potential FCOI; or
 - i. Reporting of the FCOI to the agency or entity that supports such Research or made such grant, including, but not limited to, PHS.
6. The Conflict Committee shall prepare and forward the draft Plan to the Principal Investigator of the Research in question and conflicted Investigator(s) for review and input. The Conflict Committee shall review and approve the final Plan.
 7. The Conflict Committee shall forward the approved Plan to the Principal Investigator of the Research in question and the conflicted Investigator(s).
 8. Unless notified otherwise by PHS and as long as the Investigator follows the Plan set forth by the Conflict Committee, the Investigator may proceed with participation in Center Research. The Investigator may not participate in Research until the FCOI has been managed, reduced or eliminated.
 9. If, during the course of ongoing PHS-funded Research, a new Investigator participating in the Research discloses an Investigator SFI or an existing Investigator discloses a new Investigator SFI to the Designated Official, Compliance Office, Conflict Committee or the Center, the Designated Official and the Compliance Office will, within sixty (60) days, review the Investigator SFI, determine if an FCOI exists, implement a Plan if necessary and take any other action as he or she deems necessary.
 10. A report of actions taken by the Conflict Committee will be presented to the Corporate Compliance Steering Committee on a periodic basis.

E. Appeals

Any conflicted individual who disagrees with the findings of the Conflict Committee regarding an FCOI may request an independent review of the findings by the Center Director or designee. The decision of the Center Director or designee shall be final.

F. Reporting FCOIs

The Conflict Committee shall forward the approved Conflict of Interest Management Plan to any other committees or Offices as required for additional reporting. These include:

1. The Office of Sponsored Research for sponsor notification.
 - a. The Office of Sponsored Research will submit either the FCOI Report or the Conflict of Interest Management Plan to the PHS Awarding Component prior to any expenditure or within sixty (60) days if a new FCOI arises.
 - b. The Financial Conflict of Interest Report submitted to the PHS Awarding Component must (a) include sufficient information for PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the Conflict of Interest Management Plan, (b) include the name of the individual or entity with which the Investigator has an Investigator SFI creating the FCOI, and (c) be updated annually.
 - c. For any FCOI previously reported by the Center with regard to an ongoing PHS-funded research project, the Center shall provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOI 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 FCOI no longer exists. The Center shall provide annual FCOI Reports to the PHS Awarding Component for the duration of the project
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period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

2. Regulatory committees as applicable.
 - a. Institutional Review Board; and
 - b. Institutional Animal Care and Use Committee.

G. Conflict Committee

1. If a member of the Conflict Committee is currently an Investigator participating in Research that is under review by the Conflict Committee, or if the member's impartiality is in some other way compromised, the member shall not participate in the review of that particular potential FCOI or Investigator SFI.
2. The Chair of the Institute Board of Directors of the Center will appoint an ad hoc committee to review a potential FCOI pertaining to an Institutional SFI in the event that the impartiality of the Conflict Committee could be compromised in the review of that particular potential FCOI.

H. Training

1. Each Investigator on PHS-funded Research must complete training provided by the Center regarding the disclosure of FCOIs and SFIs prior to engaging in PHS-funded Research, at least every four (4) years thereafter, and immediately (within 30 days) when any of the following circumstances apply:
 - a. The Center revises this Policy or its procedures regarding the disclosure of SFIs or FCOIs in any manner that affects the requirements of the Investigators;
 - b. An Investigator is new to the Center; or
 - c. The Center finds that an Investigator is not in compliance with this Policy or the applicable Plan.
2. Training for other Investigators will be provided as deemed necessary by the Conflict Committee.

I. Failure to Comply

1. Failure to comply with the FCOI provisions of this Policy may subject an Investigator to disciplinary action, including, but not limited to, the imposition of sanctions, termination from the Center or suspension or termination of participation in particular Research or all Research undertaken at the Center. Investigators who fail to disclose Investigator SFIs may be required to disclose the resulting FCOI in every public presentation of the applicable study and provide an addendum to previously published results.
 2. If the failure of an Investigator to comply with the FCOI provisions of this Policy is determined by the Conflict Committee to have biased the design, conduct, or reporting of PHS-funded Research, the Center will promptly notify the PHS Awarding Component of the corrective action taken or to be taken as described below. The Center and the Investigator will comply with any action taken or direction given by the PHS Awarding Component for maintaining the objectivity in related Research.
 3. Where an Investigator SFI exists that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Center, the Compliance Office and the Conflict Committee, in accordance with the procedures set forth in this Policy, shall within sixty (60) days review the Investigator SFI and determine whether an FCOI exists.
 4. If an FCOI exists that is related to PHS-funded Research but was not previously reviewed by the
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Center, the Conflict Committee shall, within those sixty (60) days, implement a Conflict of Interest Management Plan and provide to the PHS Awarding Component an FCOI Report, if an FCOI Report was not previously provided to the PHS Awarding Component.

5. If an FCOI exists that is related to PHS-funded Research and that was not identified or managed in a timely manner, the Center shall, within one hundred twenty (120) days of the Center's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The Center will document the retrospective review process, which documentation will include, but not necessarily be limited to, the following information:
 - a. Research project number;
 - b. Research project title;
 - c. Name of the project director or Principal Investigator;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has an FCOI;
 - f. Reason for the retrospective review;
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - h. Findings of the retrospective review; and
 - i. Conclusions of the retrospective review.
6. Based on the results of the retrospective review, the Center will update the FCOI Report previously submitted to PHS, if appropriate, specifying the actions that will be taken to manage the FCOI going forward. The Center will then submit FCOI Report updates annually thereafter in accordance with the federal regulations and this Policy.
7. If bias resulting from the non-disclosure is found by the Conflict Committee during the retrospective review, the Center will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include the following:
 - a. Key elements documented in the retrospective review;
 - b. A description of the impact of the bias on the Research (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research is salvageable);
 - c. The Center's plan to eliminate or mitigate the effect of the bias ; and
 - d. Any additional interim measures deemed necessary by the Center.

Forms

N/A



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Related Information

N/A

Education

Mandatory Training

Definitions

Actionable Financial Interest or AFI– An SFI that is not determined to be an FCOI and warrants certain measures to reduce the potential for bias resulting from the SFI.

Center – The H. Lee Moffitt Center and Research Institute, Inc. (the “Institute”), its subsidiary corporations and officials acting on their behalf.

Center Official – An officer of the Center.

Center Responsibilities – An Investigator's professional responsibilities on behalf of the Center under this Policy, which may include activities such as research, research consultation, teaching, professional practice, Center committee memberships, and service on panels such as Institutional Review Boards or other boards.

Conflict Committee – The committee, which determines if an FCOI exists, and/or reviews, approves with modifications, approves, or rejects actions to manage, reduce or eliminate the FCOI, pursuant to this Policy. The composition includes, but is not limited to, Corporate Compliance Steering Committee members and other individuals recommended by the Corporate Compliance Steering Committee, including Faculty members.

Conflict of Interest Disclosure Statement – The report of SFIs and other related interests to be submitted internally at the Center that will include sufficient information to enable the Center to understand the nature and extent of the SFI in accordance with this Policy.

Conflict of Interest Management Plan or Plan – A plan approved by the Conflict Committee, including the Designated Official, and agreed to by the conflicted Investigator(s) of the Research for the management, reduction or elimination of an FCOI, which describes the nature and magnitude of the SFI that has caused the FCOI to arise, and the strategies for the management, reduction or elimination of the FCOI based on the totality of the circumstances surrounding the disclosure pertaining to the Investigator and the Center, the particular FCOI, and the Research.

Designated Official – A member of the Conflict Committee, as designated by the Conflict Committee from time to time, who will review the applicable financial disclosures by an Investigator and determine, with the assistance of the full Conflict Committee, whether any Investigator SFI is related to PHS-funded Research by making a reasonable determination that the Investigator SFI could be affected by the PHS-funded Research or is in an entity whose financial interest could be affected by the PHS-funded Research.

Financial Conflict of Interest or FCOI – An SFI that could directly and significantly affect the design, conduct or reporting of Center Research.

Financial Conflict of Interest Report or FCOI Report – The report of an FCOI related to PHS-funded Research to be submitted to PHS that will include sufficient information to enable PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the Center's Conflict of Interest Management Plan, including without limitation, the following:

1. Research project number;



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2. Name of the project director or Principal Investigator;
3. Name of the Investigator with the FCOI;
4. Name of the entity with which the Investigator has an FCOI;
5. Nature of the SFI;
6. Value of the SFI in dollar ranges (\$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;
7. A description of how the SFI relates to the PHS-funded Research and the reason the Center determined that the SFI conflicts with such Research;
8. A description of the key elements of the Conflict of Interest Management Plan.

Institutional Significant Financial Interest or Institutional SFI – Anything of the Center of monetary value, including, but not limited to, payments for services, equity interests, stocks, stock options or other ownership interest, and intellectual property rights that may impact Research. Institutional SFIs include direct or indirect receipt of:

1. Equity interests including, but not limited to, stocks, stock options, or other ownership interests in a publicly traded company that, when valued in reference to current public prices, exceed \$100,000 in value.
2. Any equity interests including, but not limited to, stocks, stock options, or other ownership interests in a non-publicly traded entity.
3. Intellectual property rights, including patents, copyrights, and royalties from such rights, upon receipt of royalties or income related to such rights or other compensation from the sale of the investigational product.
4. Other related interests or activities of the Center that could affect, or be perceived to affect, the results of the Research or educational activities funded or proposed for funding, including, but not limited to, a position as a director, officer, partner, trustee, or member of a board of directors of a business entity.
5. When a Center Official, whether participating in Research or not, holds an SFI in any non-Center entity.

This list is not exhaustive of all financial relationships warranting scrutiny by the Compliance Office or the Conflict Committee.

Investigator – The Principal Investigator based at the Center and any other individual based at the Center, including without limitation, a project director or Key Personnel, who is responsible for the design, conduct or reporting of Research at the Center, regardless of such individual's title or position and regardless of whether or not the individual is an employee of the Center. Investigator also means any Center employee based at a facility other than the Center who is responsible for the design, conduct or reporting of Research and who is not subject to that facility's conflict of interest policy. For purposes of identifying individuals who shall complete and submit a Conflict of Interest Disclosure Statement, "Investigator" also means all individuals at a director level and above, H. Lee Moffitt Cancer Center and Research Institute Lifetime Cancer Screening Center, Inc. d/b/a Moffitt Medical Group ("MMG") clinical faculty and advanced practice professionals, Moffitt Genetics Corporation ("M2Gen") staff, and Institute staff, as deemed appropriate.

Investigator Significant Financial Interest or Investigator SFI –

1. Anything of monetary value, whether or not the value is readily ascertainable, consisting of one
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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 Center Responsibilities:

- i. With regard to any **publicly traded entity**, an Investigator SFI 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 Policy, 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;
 - ii. With regard to any **non-publicly traded entity**, an Investigator 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 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
 - iii. **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests when aggregated, exceeds \$5,000.
2. An Investigator involved in PHS-funded Research must disclose, as an Investigator SFI, 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 or her Center Responsibilities, in the twelve months preceding the disclosure, regardless of whether the amount of reimbursed or sponsored travel exceeds \$5,000; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The Investigator shall include in his or her disclosure to the Designated Official and the Compliance Office the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and any other information requested by the Designated Official, the Compliance Office or the Conflict Committee.
 3. Notwithstanding anything in this Policy to the contrary, the term Investigator SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Center, including intellectual property rights assigned to the Center and agreements to share in royalties related to such rights; any ownership interest in the commercial or for-profit subsidiaries of the Center held by the Investigator; 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 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 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.

This list is not exhaustive of all financial relationships warranting scrutiny by the Designated Official, the Compliance Office or the Conflict Committee. All potential Investigator FCOI must be brought to the Designated Official and Compliance Office for assessment.



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Key Personnel – The project director or Principal Investigator and any other individual identified as senior or key personnel in a grant application, any progress report, or any other report submitted by the Center to the PHS pursuant to this Policy.

Key Personnel Significant Financial Interest Information – The information related to an Investigator SFI that shall be publicly disclosed in compliance with the federal regulations prior to the Center's expenditure of any PHS funds for Research, including without limitation, the Investigator's name, the Investigator's position with respect to the Research, the name of the entity in which the Investigator SFI is held, the nature of the Investigator SFI, and the approximate dollar value range of the Investigator SFI (\$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.

Notice of Award – The official PHS grant award document notifying the grantee and others that a grant has been made.

PHS – The Public Health Service, a division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

Policy – This Conflict of Interest in Research Policy.

Principal Investigator – The individual who is the responsible leader of the team of Investigators and personnel undertaking Research at the Center.

Research – A systematic investigation designed to develop or contribute to generalizable knowledge and a fuller scientific understanding of the subject studied, encompassing basic and applied research and product development.

Significant Financial Interest or SFI – Individually or collectively, an Institutional SFI and/or an Investigator SFI.

Subrecipients – Subgrantees, contractors or collaborators that carry out Research on behalf of the Center.

References

[42 CFR Part 50, Subpart F](#)

[45 CFR Part 94](#)

[45 CFR Part 74](#)

[21 CFR Part 54.2](#)

[National Science Foundation Investigator Financial Disclosure Policy](#)

Appendices

N/A

Revision History

09/2005, 01/2009, 05/2011, 08/2012, 07/2014, 07/2016