

Policy Title: Research - Financial Conflicts of Interest
Category/Subcategory: Corporate - Compliance/Legal
Approver(s): Vice President of Senior Legal Counsel & Compliance Officer
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I. Policy Statement and Purpose.

The purpose of this policy is to establish guidelines for complying with applicable regulations relating to Financial Conflicts of Interest (“FCOI”) in research. No research activities involving PM Pediatric Care shall be adversely affected by the Financial Interests of any persons involved in such research activities.

Any individual possessing a Financial Interest related to their involvement with the research must disclose their interests prior to participating in the research activity, annually thereafter, or within 30 days of any new or revised interests. All Disclosures will be reviewed in accordance with this policy and a plan for the elimination or management of any Financial Conflicts of Interest will be instituted.

II. Definitions.

“PM Pediatric Care” refers to PM Pediatrics Management Group, LLC, its affiliates and subsidiaries, as well as all medical practices under management by PM Pediatrics Management Group, LLC.

Covered Persons: For purposes of this policy, Covered Persons are defined as one of the following:

1. **Investigators:** The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
2. **Senior/Key Personnel:** The Project Director/Principal Investigator and any other person who is identified as Senior/Key Personnel in the grant application, progress report, and any other report submitted to the Public Health Service (“PHS”).

Disclosure: For purposes of this policy, the term Disclosure refers to either:

1. Internal reporting of Financial Interests by Covered Persons.
2. External reporting about a Covered Person’s Financial Interests where relevant (e.g., to research subjects, research funders, in publications and presentations).

Equity Interest: Any Financial Interest in the profits of, or stock of, a commercial or non-profit enterprise, a stock option, or any other ownership interest in a commercial or non-profit enterprise.

Entity: Any domestic or foreign, public or private, for profit or non-profit legal entity or organization other than PM Pediatric Care, any State agencies, or the Federal government.

Family Member: A Covered Person's spouse, domestic partner, or dependent children.

Financial Conflict of Interest (FCOI): A significant financial interest that is related to and could directly and significantly affect the design, conduct, or reporting of the Research.

Financial Interest: Anything of economic or monetary value, whether the value is readily ascertainable, possessed by a Covered Persons and/or their Family Member(s).

Intellectual Property (IP): Pending or issued patents, copyrights, or trademarks, and all rights to share in the royalties from or income produced by any of the foregoing under licenses, contracts or otherwise, whether accrued or contingent.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional Responsibilities: A Covered Person's professional responsibilities on behalf of the Institution which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Management Plan: A written plan to address a Financial Conflict of Interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

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 involved may be delegated, including the National Institutes of Health ("NIH").

PHS Awarding Component: the organizational unit of the Public Health Service that funds Research that is subject to 42 CFR 50, subpart F.

PHS-Funded Research: any research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award. PHS-Funded Research does not include any Phase I SBIR Program application or award.

Significant Financial Interest means:

(1) A Financial Interest consisting of one or more of the following interests of the Covered Person (and those of the Covered Person's spouse, domestic partner, and dependent children) that reasonably appears to be related to the Covered Person's Institutional Responsibilities:

(i) 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;

(ii) 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 Covered Person (or the Covered Person's spouse, domestic partner, 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.

(2) Covered Persons also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Covered Person and not reimbursed to the Covered Person so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; 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 Disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

(3) The term Significant Financial Interest does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by the Institution to the Covered Person if the Covered Person is currently employed or otherwise appointed by the Institution, including Intellectual Property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Covered Person, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Person 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.

III. Policy.

A. Covered Persons Responsibilities. All Covered Persons are required to do the following:

1. Disclose Financial Interests:
 - a. Prior to the submission of a grant proposal/application.
 - b. Annually.
 - c. Within 30 days of discovering or acquiring a Financial Interest.
 - i. For Sponsored or Reimbursed Travel, the Disclosure must be made within 30 days of the trip's end.
2. Certify that their Disclosure is current at the time of submission of a grant proposal/application.
3. Ensure that their Disclosure is current prior to the approval and throughout the lifecycle of the research.
4. Disclose individual or Family Members' Financial Interests that reasonably appear to be related to their research responsibilities or have a Significant Financial Interest (as defined in this

policy) in an Entity that is sponsoring the research, or an Entity that is manufacturing the product or service being tested.

5. Comply with any Management Plan established because of an identified Financial Conflict of Interest.
6. Complete required Financial Conflict of Interest training:
 - a. PM Pediatric Care offers FCOI training through the Learning Management System. Per Federal regulations and PM Pediatric Care policies, Covered Persons are required to complete FCOI training:
 - i. During the on-boarding process.
 - ii. Every 4 years.
 - iii. As mandated by PM Pediatric Care, upon determination of non-compliance with this policy or an existing Management Plan.
 - iv. When PM Pediatric Care revises this policy in any manner that affects the requirements of Covered Persons.

B. Principal Investigator Responsibilities. In addition to the responsibilities outlined for all Covered Persons above, Principal Investigators (“PI’s”) are required to:

1. Ensure all Covered Persons involved in a research project have a current Financial Interest Disclosure on file prior to their participation in the project.
2. Ensure all Covered Persons involved in a research project promptly disclose any new or updated Financial Interests.
3. Ensure all Covered Persons involved in a research project have completed the FCOI training required under this policy.
4. Indicate, upon submission of a proposal/application, if they or any project Covered Persons have any Financial Conflicts of Interest that may be related to the proposed project.

C. Review of Disclosures.

1. All Disclosures will be reviewed in accordance with the Company’s process for reviewing general conflicts of interest to determine if the Financial Interest is related to the Covered Person’s research and rises to the level of a Significant Financial Interest.
 - a. If additional information is needed during the review process, a request for clarification will be sent to the Covered Person.
 - b. Depending on the nature of the Financial Interest, interim measures may be implemented regarding the Covered Person’s participation in the research project between the date of Disclosure and the completion of the Significant Financial Interest review.
 - a. A summary of the measures required to manage the Significant Financial Interest will be provided as an interim plan to the Covered Person and Institutional Review Board (IRB) of record.

D. Management of Financial Conflict of Interest.

1. If a FCOI is identified, a Management Plan will be developed. FCOI Management Plans will address the following key areas: 1) The nature of the conflict; 2) the relation of the conflict to the research; 3) the perceived risk to the integrity of the research as a result of the conflict; 4)

if applicable, the specific risks to human subjects; 5) if the conflict can be managed by a Management Plan; and 6) the perceived risk to sufficiently protect the reputation of the Institution.

2. Management Plans may include the following terms and conditions:
 - a. Disclosure of Financial Interest(s) relating to the conflicted research study(ies) in publications, presentations, and any public communication of research results.
 - b. Disclosure of Financial Interest(s) relating to the conflicted research study(ies) to all research personnel affiliated with and potential human subjects participating in the research.
 - c. Prohibition from obtaining informed consent of human subject participants.
 - d. Prohibition from production of data involving subjective scoring or similar methods.
 - e. Prohibition from conducting data analysis.
 - f. Prohibition from performing adverse event causation analysis.
 - g. Prohibition from using PM Pediatric Care assets and facilities relating to conflicted Entity(ies).
 - h. Prohibition from participating in negotiations on behalf of PM Pediatric Care and conflicted Entity(ies).
 - i. Prohibition from disclosing proprietary information belonging to PM Pediatric Care to conflicted Entity(ies).
 - j. If the individual is a decision maker, recuse oneself from making future decisions on behalf of PM Pediatric Care relating to the Financial Interest(s).
 - k. Update the Disclosure within 30 days of known change in Financial Interest(s).
 - l. Upon request, make available all research data and results for independent data monitoring.
 - m. Upon request, provide information for independent review of study design.
3. All FCOIs must be submitted to the IRB of record.
 - a. FCOIs identified due to an updated Disclosure after a study is approved, may result in IRB activity holds until the conflict is resolved.
4. For PHS-funded research, the actions taken upon Disclosure and/or implementation of a Management Plan will be completed prior to the expenditure of any research project funds, or within 60 days of a Disclosure of a FCOI during a research project by an existing Covered Person or a Covered Person new to the project.
5. Whenever a Management Plan is implemented, PM Pediatric Care shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan, including obtaining regular reports from individuals charged with oversight responsibilities in connection with FCOI Management Plans. This audit and/or monitoring of compliance will be conducted until the completion of the research project or until the Management Plan is no longer required.

E. Management of Other Interests.

1. When a Disclosure is determined not to constitute a Significant Financial Interest, PM Pediatric Care may determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. PM Pediatric Care may specify additional terms and conditions to manage these other interests.

F. FCOI Reporting to PHS Awarding Components for PHS-Funded Research.

1. FCOI reports will be submitted to a PHS Awarding Component:
 - a. Prior to expenditure of any funds under a PHS-funded research project, if an FCOI has not been eliminated.
 - b. Within 60 days of identifying an FCOI during any ongoing research project.
 - c. Annually for any FCOI previously reported regarding an ongoing PHS-funded research project. The report shall specify the status of the FCOI (if the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the research project at the same time as the submission to NIH of the annual progress report, multi-year progress report, if applicable, or at the time of extension.
2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50, Subpart F and contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the Management Plan.

G. Subrecipient Requirements.

1. PHS-Funded Research that is carried out in which PM Pediatric Care is a Subrecipient will be done so in accordance with 42 CFR Part 50, Subpart F. As such, any written agreement will include:
 - a. Terms that establish whether the awardee or Subrecipient's FCOI policy will apply to the Subrecipient Investigators.
 - b. Time period(s) for the Subrecipient to report all identified FCOI.

H. Public Accessibility Requirements.

1. This policy shall be available via PM Pediatric Care's publicly accessible web site.
2. For PHS-Funded Research, PM Pediatric Care shall make information concerning Significant Financial Interests that meet the criteria below available to the public, upon written request for such information:
 - a. The Significant Financial Interest was disclosed and is still held by the Covered Person.
 - b. It is determined that the Significant Financial Interest is related to a PHS-Funded Research project.
3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F and shall be provided by written response to the requestor.
4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.

I. Retrospective Reviews.

1. If it is identified that a Significant Financial Interest was not disclosed in a timely manner or was not previously reviewed during an ongoing PHS-Funded Research project, PM Pediatric Care shall within 60 days:
 - a. Review the Significant Financial Interest.
 - b. Determine whether it is related to a PHS-Funded Research project.

- c. Determine whether an FCOI exists.
 - d. If it is determined that an FCOI exists, a Management Plan will be implemented that specifies the actions that have been taken and will be taken to manage such FCOI.
2. Whenever an FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to non-compliance by a Covered Person, including if the Covered Person fails to comply with a Management Plan:
 - a. A retrospective review will be completed and documented of the Covered Person's activities and the research project within 120 days of the non-compliance identification, Documentation of the review will include all elements as specified by 42 CFR Part 50, Subpart F.
 - b. Based on the results of the retrospective review, if appropriate, the previously submitted FCOI report will be updated and specify the actions that will be taken to manage the FCOI moving forward.
 - c. If bias is found, the PHS Awarding Component will be promptly notified, and a mitigation report will be developed and submitted. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F.
 - d. FCOI reports will be submitted to the PHS Awarding Component annually thereafter for the duration of the research project.

J. Sanctions for Noncompliance.

1. If it is determined that a Covered Person has violated this policy, including failure to submit required Disclosures or failure to comply with the requirements of a Management Plan, reasonable steps will be taken to respond appropriately to the violations, including, but not limited to:
 - a. Suspending research activity expenditures.
 - b. Administratively suspending any research study related to the FCOI.
 - c. Instituting disciplinary measures up to and including suspension or termination.
2. If required to do so, PM Pediatric Care will submit to HHS, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.
3. In the case in which it is determined that a PHS-Funded Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Person with an FCOI that was not managed or reported, the Covered Person involved shall be required to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.

K. Maintenance of Records.

1. PM Pediatric Care shall maintain records relating to:
 - a. All Covered Person Disclosures of Financial Interests.
 - b. All review and response to such Disclosures.
 - c. Actions taken under this policy or retrospective reviews.
2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or as

required by 45 CFR 74.53(b) and 92.42(b). For all other research, these records will be maintained for at least three years from the date of the final expenditures report.