

FINANCIAL CONFLICT OF INTEREST POLICY

Public Health Services

SECTION 1 – OVERVIEW, APPLICABILITY AND RESPONSIBILITIES

1.1 Statement of Background and Purposes

The United States Department of Health and Human Services (DHHS) has amended its regulations (set forth in 42 CFR chapter I, subchapter D, part 50, and 42 CFR subtitle A, subchapter A, Part 94) (the Amended Regulations) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements, or performed under PHS contracts will be free from bias resulting from investigator financial conflicts of interest. This policy confirms the commitment of Philadelphia College of Osteopathic Medicine (PCOM) to the basic values of openness, academic and scholarly integrity and objective and ethical research and is intended to conform PCOM policy to the Amended Regulations and to supplement the existing Code of Conduct and Conflict of Interest policies and procedures of PCOM.

In addition to supporting the basic values of PCOM, this policy is also designed to:

- Identify and eliminate or manage any possible threat to the objectivity of research performed at PCOM in connection with grants and sponsored projects funded by PHS/DHHS and PHS/DHHS-funded agencies (which include but are not limited to grants or sponsored projects funded by the National Institutes of Health (NIH), or under PHS contracts.
- Satisfy the Amended Regulations requiring the PCOM to establish and implement policies concerning Significant Financial Interests held by:
 1. Personnel engaged in research funded by certain federal agencies, e.g., Public Health Services (Title 42 CFR Part 50, Subpart F and 45 CFR Part 94) and the National Science Foundation (Award and Administration Guide),
 2. Institutional Review Board members (Title 45 CFR Part 46.107(e)), and
 3. Any personnel who may become involved in research involving human subjects funded by the Department of Health and Human Services.
- Protect researchers and other Employees from misplaced charges of Financial Conflicts of Interest by providing a mechanism for prior objective review and approval of Financial Interests.

1.3 Applicability

This policy applies to all research grants and sponsored projects funded or proposed to be funded by PHS/DHHS-funded agencies, including but not limited to the National institutes of Health, and to research performed in connection with PHS/DHHS contracts.

Furthermore, the policy applies to Project Directors, Principal Investigators, and any other Senior/key personnel (as defined below) on the grant or sponsored project, and all subrecipients related to NIH funded grants and sponsored projects funded or proposed to be funded by a PHS Agency.

Subrecipients on PHS/DHHS-funded projects are subject to and required to comply with and follow the regulations as set forth in Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F and 45 CFR Part 94), even though the subrecipients are not directly awarded the funds from PHS or any PHS/DHHS agency. Subrecipients must demonstrate or provide adequate assurances that the policies and procedures of their institutions are in compliance with the regulation.

Dept. of Health and Human Services (DHHS) / Public Health Services (PHS) Agencies:

Administration for Children and Families (ACF)
Administration on Children, Youth and Families (ACYF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry (ATSDR)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Services (IHS)
National Institutes of Health (NIH)
National Cancer Institute (NCI)
Substance Abuse and Mental Health Services Administration (SAMHSA)

1.4 Definitions

Audit Committee

The Audit Committee of Philadelphia College of Osteopathic Medicine Foundation.

Board of Trustees

The Board of Trustees of PCOM.

Disclosure Review Committee

PCOM's existing Institutional Compliance Committee, which is chaired by PCOM's Institutional Compliance Officer, shall serve as the Disclosure Review Committee.

COI Officer

The Financial Conflict of Interest Officer, who will be the Director of Research and Sponsored Programs or his or her designee.

Dependent

An Employee's spouse, Domestic Partner or unemancipated child(ren), including stepchildren

and adoptees, under the age of 18, or anyone who receives more than one-half of his or her financial support during a year from an Employee.

Domestic Partner

A same sex domestic partner of an Employee.

Employee

Any employee of PCOM, wherever located and whether full-time or part-time, including, but not limited to, all executive officers, faculty and staff.

Equity Interest

Any ownership interest in a company or business, including, but not limited to, stocks, stock options or warrants, membership or partnership interests or rights, and similar interests.

Financial Conflict of Interest

Situations where an Employee's Financial Interest (including an Investigator's Significant Financial Interest, where applicable) compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Financial Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence PCOM's business, research or decisions in ways that could lead directly or indirectly to financial gain for the Employee or the Employee's Dependents or could give an improper advantage to others to the detriment of PCOM.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator's Financial Interest (including Significant Financial Interest) compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if such Financial Interest could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods.

Financial Conflicts of Interest also include the use of PCOM facilities, personnel, equipment, Information Technology Resources, confidential information or other resources for purposes that could lead directly or indirectly to financial gain for the Employee and/or his or her Dependents.

Financial Interest

Any interest that will, could, or is intended to lead to a profit or an ascertainable increase in the income or net worth of an Employee and/or a Dependent. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including, but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

Institutional Responsibilities

An Employee or Investigator's professional responsibilities on behalf of PCOM, including, but not limited to, 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.

Intellectual Property Rights

Any interest in intellectual property, including, but not limited to, patents, copyrights, licenses, royalties from such rights, agreements to share royalties and similar interests.

Investigator

A project director, a principal investigator of a research project and any other person, regardless of title or position, who has responsibility for the design, conduct or reporting of research or project results at or involving PCOM, including Employees, subgrantees, contractors, subcontractors, collaborators and consultants. In general, any individual specifically named in a proposal and any individual whose resume or curriculum vitae is appended to a proposal is an Investigator for the purposes of this policy.

Management Plan

A plan specifying the actions to be taken to manage an identified Financial Conflict of Interest.

PD

A Project Director.

PI

A Principal Investigator.

President

PCOM's President.

Provost

PCOM's Senior Vice President for Academic Affairs and Provost.

PCOM

Any campus, unit, program, or entity of Philadelphia College of Osteopathic Medicine or Philadelphia College of Osteopathic Medicine Foundation.

Regulatory Committee

Any PCOM committee or board with regulatory oversight responsibilities, including any Institutional Review Boards or similar board or committee.

Research

A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). This includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel

The Program Director, Principal Investigator and any other person identified by PCOM in a grant application, progress report and any other report submitted to the PHS (or other grant provider) by PCOM.

Significant Financial Interest

A Financial Interest held by an Investigator and/or an Investigator's Dependent that reasonably appears to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, and paid authorship) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds \$5,000;
- Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000;
- Any Equity Interest in a non-publicly traded company or business, regardless of value; and
- Any Intellectual Property Rights, regardless of value.

Significant Financial Interest does not include:

- An Employee's salary or royalties received from the PCOM,
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an institution of higher education, or
- Income from service on panels for a federal, state or local government agency or institution of higher education.

ICO

PCOM's Institutional Compliance Officer.

1.4 Exceptions

Exceptions to this policy are applications for Phase I support under the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs.

1.5 Project Directors, Principal Investigators, Senior/Key Personnel Responsibilities

Project Directors, Principal Investigators and other Senior/key personnel are expected to adhere and conform to the requirements as set forth in the policy. Project Directors, Principal Investigators and other Senior/key personnel will be referred to as investigators in the body of this policy.

1.6 Responsibilities

PCOM

PCOM and its assigned designees are responsible for the overall management and administration of the Financial Conflict of Interest Policy. PCOM will maintain and post on its internet Web site a written and enforced policy related to the amended federal Financial Conflict of Interest regulations (FCOI Regulations) and will be responsible for informing Investigators of the FCOI Regulations, PCOM's Financial Conflict of Interest policy, and Investigators' disclosure responsibilities under the FCOI regulations and PCOM's Financial Conflict of Interest policy.

Disclosure Review Committee

The Disclosure Review Committee shall review and make determinations about Financial Conflicts of Interest. In the course of reviewing a Significant Financial Interest, the Disclosure Review Committee will determine how the significant financial interest is tied to activities within an Investigator's field of scientific expertise or medicine as well as teaching, clinical, administrative and purchasing responsibilities. The Disclosure Review Committee shall be under the supervision of and report to the Audit Committee. PCOM, in its Institutional responsibilities, may employ and seek review and approval of an Investigator's significant financial interests disclosed to the committee from the dean of his or her school and/or chair/chief of his or her department or division.

COI Officer

The COI OFFICER shall solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in PHS/DHHS- funded research. In addition to his or her other duties, the COI OFFICER shall solicit and oversee the receipt and review of disclosures of Significant Financial Interests related to (i) proposing, conducting or reporting of PCOM research or scholarship, (ii) research regulatory compliance and (iii) commercialization of PCOM's intellectual property and the management of real or potential Conflicts of Interest arising from these disclosed Significant Financial Interests.

Coordinate the development and oversight of appropriate Management Plans for Financial Conflicts of Interest when appropriate. Report annually to the Disclosure Review Committee on identified real or potential Financial Conflicts of Interest associated with research, programs or contracts; the status of Management Plans implemented to manage or reduce these Conflicts of Interest; and compliance with applicable federal requirements and PCOM policies.

SECTION 2 – DISCLOSURE, REVIEW AND MANAGEMENT PLANS

2.1 Disclosure Process

Investigators identified in each grant and sponsored project funded or proposed to be funded by any PHS/DHHS agency shall disclose all Significant Financial Interests that are related to their Institutional Responsibilities and expertise.

Travel

Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. (Sponsored travel is travel which is paid for on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value is/may not be readily available.) PCOM may inquire about and request additional information related to travel disclosed by the Investigator on disclosure forms.

Travel does not include travel 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
- A Research institute that is affiliated with an institution of higher education

Consulting Agreements and Engagements

Special attention must be paid to consulting agreements and engagements. If the consultation appears to be related to the Investigator's Institutional Responsibilities, then that consulting agreement and engagement must be disclosed on the Significant Financial Interest Disclosure Form regardless of monetary value or aggregated value of remuneration received in the preceding 12-month period or as of the date of disclosure.

A Significant Financial Interest Disclosure Form must be completed and provided to the Office of Research and Sponsored Programs by each Investigator:

- After receiving notice of award from the PHS/DHHS agency, but prior to the use of awarded funds.
- Annually, during the period of the award. Annual progress reports require Financial Conflicts of Interest to be disclosed.
- Within 30 days of discovering or acquiring a new Significant Financial Interest as defined above; examples include, but are not limited to, purchase, marriage, inheritance, etc.

Any new Investigator assigned to or joining the research project during either the pre-award or post-award stage of a project shall also complete and provide a Significant Financial Interest Disclosure Form to the Office of Research and Sponsored Programs..

PCOM, in the course of its duties and responsibilities, may identify a Significant Financial Interest that has not been reported by the Investigator(s). If a Significant Financial Interest is identified by the Disclosure Review Committee, then the Disclosure Review Committee will conduct a review of the Significant Financial Interest and determine if a Financial Conflict of Interest exists. If the Significant Financial Interest is determined to be a Financial Conflict of Interest, then a retrospective review of the project must occur to determine if bias exists in the research.

2.3 Review of Disclosures

The Disclosure Review Committee (DRC) will review all Significant Financial Interest Disclosures. The committee will be responsible for determining whether the Significant Financial Interests of the Investigator and/or the Investigator's Dependents could reasonably be expected to affect the design, schedule, implementation, and/or reporting of the activities funded or proposed for funding. When the committee makes a determination that a Significant Financial Interest may compromise the integrity and objectivity of the research as described above, then the Significant Financial Interest becomes a Financial Conflict of Interest (FCOI). The committee may request additional clarifying information, as well as a proposed Management Plan for the conflict, from the Investigator(s), which will be treated as non-public information to the extent allowed by law. Upon completion of its review, the committee will advise the President of PCOM and the Audit Committee of its findings.

During the review of the Investigator's Significant Financial Interest Disclosure, the Disclosure Review Committee may employ and seek further assistance and clarification from the Investigator(s) or other institutional employees whose knowledge and skill set relate to the research.

2.4 Retrospective Review

If a Financial Conflict of Interest is not identified or managed in a timely manner, PCOM will within 120 days of making a determination of noncompliance, conduct and complete a

retrospective review of the Investigator's activities and the PHS/DHHS-funded project to determine whether any PHS/DHHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. Examples of noncompliance include, but are not limited to:

- Failure by an Investigator to disclose a Significant Financial Interest determined by PCOM to constitute a Financial Conflict of Interest
- Failure by PCOM to review or manage a Financial Conflict of Interest
- Failure by an Investigator to comply with a Management Plan
- Management Plan is determined to have biased the design, conduct, or reporting of the PHS/DHHS-funded research

Each Retrospective Review shall be documented in accordance with applicable DHHS regulations, and such documentation shall include, but shall not be necessarily limited to the following key elements: (1) Project number, (2) Project Title, (3) PD/PI, (4) Name of the Investigator with the FCOI, (5) Name of the entity with which the Investigator has a FCOI, (6) Reason(s) for the retrospective review, (7) Detailed methodology used for the retrospective review, (8) Findings of the review, and (9) Conclusions of the review.

If appropriate, based upon the results of the retrospective review, PCOM shall update any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found during the course of the retrospective review, then PCOM will promptly notify and submit a mitigation report to the PHS Awarding Component, which mitigation report shall include at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and PCOM's action(s) taken to eliminate or mitigate the effect of the bias. Furthermore, if the Department of Health and Human Services determines that a PHS/DHHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the institution as required by the regulation, the institution shall require the Investigator to do the following:

- Disclose the FCOI in each public presentation of the results of the research
- Request an addendum to previously published presentations

2.5 Management Plans for Conflict

If after reviewing all Investigator disclosures of Significant Financial Interests, the Disclosure Review Committee determines that a FCOI exists with respect to a PHS/DHHS-funded project, the Disclosure Review Committee will review the Management Plan proposed by the Investigator and either approve or add conditions or restrictions to ensure that any FCOI is reduced, eliminated, or managed. Such conditions or restrictions may include, but are not limited to, the following:

- Public disclosure of significant financial interests and financial conflicts of interest;
- For Research Projects involving human subjects, disclosure of FCOIs directly to participants;
- Monitoring of the research by independent reviewers;
- Modification of the planned activities (possibly subject to sponsor approval);
- Disqualification of the affected Investigator from participation in all or part of the project;
- Divestiture by the Investigator of significant financial interests;
- Severance of relationships creating the FCOI.

In all cases, resolution of the conflict or establishment of an acceptable Management Plan must be achieved and approved by the President of PCOM before expenditure of any funds under an award.

2.6 Financial Conflict of Interest (FCOI) Reporting

When a Financial of Conflict of Interest exists, then reporting of the FCOI must be performed in a timely manner and sent to the appropriate PHS/DHHS agency. Mandatory reporting of FCOIs and related documents may encompass any one of or all of the following aspects of the FCOI policy:

- Financial Conflict of Interest exists
- Management Plan
- Mitigation Report
- Noncompliance with FCOI Policy

SECTION 3 – OTHER MANAGEMENT AND ADMINISTRATION FUNCTIONS

3.1 Public Disclosure of Conflicts of Interest

Public requests to review Financial Conflicts of Interest must be made in writing and include at a minimum the following information:

- Name and address of the person requesting the information, including the address of where to send the information
- Name of Investigator(s) whose Financial Conflict of Interest information is requested

If the above information is not provided in writing, then PCOM will make an attempt to obtain that information in order to process the request. Furthermore, all public requests must be directed to the following office and address location:

Office of Research and Sponsored Programs
4170 City Avenue
Philadelphia, PA 19131

The Office of Research and Sponsored Programs must provide the requested information within 5 calendar days of receiving a public request starting on the day when all of the information from the public is received by PCOM. Investigator(s) relationships that need to be made public are only Financial Conflicts of Interest that are disclosed and continue to be held. The Office of Research and Sponsored Programs will respond to the request using the Public Request Disclosure Form.

3.2 Appeals

Appeal of the committee's decision may be made to the Audit Committee. After the Audit Committee has made a final decision, the committee will inform the Investigator.

3.3 Investigator Training

PCOM will use an online, web-based module to administer training related to the revised Financial Conflict of Interest regulation to all appropriate and applicable Investigators.

Training on Financial Conflict of Interest is mandatory for all Investigators who will propose for funding or are funded by Public Health Services (PHS) / Department of Health & Human Services (DHHS) funds or its affiliating agencies. Training is required under the following circumstances:

- Prior to engaging in covered research (PHS/DHHS Agency funded research)
- Every 4 years
- Revisions to Financial Conflict of Interest Policy and associated changes in the applicable regulations are made
- Revisions are made to procedures associated with Financial Conflict of Interest Policy, if the revised procedures affect requirements of Investigators
- The Investigator is not in compliance with PCOM's Financial Conflict of Interest Policy or with approved Management Plan(s)

3.4 Compliance

As part of the Disclosure Statement, each Investigator must certify that, if the Disclosure Review Committee determines a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

3.5 Enforcement

Failure to properly disclose relevant financial and other interests or to adhere to conditions or restrictions imposed by the Disclosure Review Committee will be considered a deviation from

accepted standards of conducting activity at PCOM, which may be subject to appropriate enforcement actions as prescribed by PCOM policy, faculty handbook, and employee contracts.

3.6 Records

Office of Research and Sponsored Programs and the Budget and Financial Planning Office will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for /a minimum of 3 years from the later of date the final expenditures report is submitted to the PHS/DHHS agency or where applicable for the other time periods specified in Title 45 – Public Welfare Act – Subchapter A: General Administration: Subparts and Sections 74.53 (b) and 92.42 (b).

Section 4 – Disclosures by Regulatory Committee Members

If a member of a Regulatory Committee recognizes that he or she has a Financial Interest in a protocol to be reviewed by that Regulatory Committee, or in an entity that may be affected by the outcome of a protocol to be reviewed by the Regulatory Committee, the committee member must:

- Inform the chairperson of the Regulatory Committee that he or she has a Financial Interest in a protocol to be reviewed.
- Recuse himself or herself from participation in the review of that protocol.
- Return to the chairperson of the Regulatory Committee all materials associated with the review of the protocol.
- Leave the committee meeting room during discussion, deliberation and voting on the protocol, both during the initial meeting and any subsequent meetings of the Regulatory Committee when the protocol is considered for purposes of initial or continuing review, for discussion of unexpected or adverse events or for non-compliance associated with the protocol.

FEDERAL REGULATIONS REFERENCES

Department of Health and Human Services. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. July 11, 1995. 60 FR 35810, Part III.

National Science Foundation. Investigator Financial Disclosure Policy. July 11, 1995.

60 FR 35810, Part III

2 CFR Par 215 - Uniform Administrative Requirements...

42 CFR Part 50 – Policies of General Applicability. Subpart F – Promoting Objectivity in Research

42 CFR Part 52 – Grants for Research Projects.

45 CFR Part 46 – Public Welfare Act. Subtitle A – Department of Health and Human Services.
Subchapter – General Administration. Parts 74 and 92.

45 CFR Part 46.107(e) – IRB Membership

For additional information, contact: Director, Research and Sponsored Programs at (215) 871-6783.