

Polisher Research Institute Financial Conflict of Interest

Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

I. PURPOSE

This policy promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator. The policy also supports the Polisher Research Institute's compliance with the Public Health Service regulations (42 CFR Part 50, Subpart F)

II. APPLICABILITY

The policy applies to all Polisher Research Institute staff, who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored project at the Polisher Research Institute.

The policy also applies to subgrantees, contractors, or collaborators of the Polisher Research Institute involved in an externally sponsored project unless individuals can provide written assurance to the Polisher Research Institute's Chief Executive Officer that they are subject to a similar financial conflict of interest policy. SUBRECIPIENT Institutions who rely on their FCOI policy must report identified FCOIs to the Polisher Research Institute in sufficient time to allow the Polisher Research Institute to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations.

This excludes applications for Phase I support under the SBIR and Small Business Technology Transfer (STTR) programs.

III. DEFINITIONS

As used in this policy:

Financial Conflict of Interest means a significant financial interest that is related to proposed Polisher Research Institute research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, in any one of the following categories: compensation; equity (stock, stock options or other ownership interest) in a public or private company; royalty/licensing income; a position in a non-PRI entity giving rise to a fiduciary duty such as director, officer, partner, trustee, employee or any position of management; or, for researchers with funding from the Public Health Service, any reimbursed or sponsored travel.

Human Subjects Research means RESEARCH (defined below) conducted with a living individual about whom an INVESTIGATOR obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, whether or not they receive salaries or compensation under the grant. For purposes of the requirements of this policy relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating 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.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy (including the National Institutes of Health).

Research means a systematic investigation 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 and product development. As used in this policy, the term 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.

Senior/Key Personnel means a PHS project director or principal investigator and any other individual who contributes to the scientific development or execution of a project in a substantive, measurable way, and who is included in the grant application, progress report, or any other report submitted by the institution, whether or not they receive salaries or compensation under the grant.

Significant Financial Interest (SFI) means anything of monetary value or potential monetary value held by an INVESTIGATOR (and by the INVESTIGATOR's spouse and dependent children), and that reasonably appears to be related to the INVESTIGATOR's institutional responsibilities, as follows:

(1) With regard to any publicly traded entity, 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 the definition of SIGNIFICANT FINANCIAL INTEREST, 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.]

(2) With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the calendar year preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest);

(3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

- (4) A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any position of management.
- (5) For Investigators applying for or conducting research funded by the PHS, any reimbursed or sponsored travel related to the INVESTIGATOR's institutional responsibilities (i.e., travel is paid on behalf of the INVESTIGATOR and not reimbursed to the INVESTIGATOR so that the exact monetary value may not be readily available). Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination.

The term SIGNIFICANT FINANCIAL INTEREST does not include salary or other remuneration paid by the Polisher Research Institute to the INVESTIGATOR if the INVESTIGATOR is currently employed or otherwise appointed by the Institute; 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, teaching engagements, or travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute 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 or institution of higher education.

IV. PROCEDURES

A. Disclosure of Financial Interests:

Each Investigator covered by this policy will report all financial interests that are both significant and related, held by themselves, their spouses, or their dependent children at the following times:

- (1) Prior to submitting a research application for outside funding,
- (2) At least annually thereafter during the period of the research activity,
- (3) At any time during the research when a new related significant financial interest is obtained (within 30 days of discovering or acquiring a new SFI).

The existence of a related significant financial interest will be indicated when proposals are being submitted, and full disclosures of such interests will be made by use of the Financial Conflict of Interest form and sent to the Chief Executive Officer and Grants Administrator for the Polisher Research Institute.

B. Review and Disposition:

(1) Determination of Significant Financial Interest

Prior to the INVESTIGATOR's expenditure of any funds, or prior to the initiation of the research in the case of research with no external funding, the Grants Administrator will review the disclosed financial interest to determine whether it constitutes a significant financial interest.

(2) Determination of Financial Conflict of Interest

Upon concluding that the disclosed financial interest constitutes a significant financial interest, the Grants Administrator will review the disclosed significant financial interest to determine whether a financial conflict of interest exists and thus whether further review and management is required.

In this review, the Grants Administrator will notify the Chief Executive Officer of the existence of the financial conflict of interest.

C. Review by Chief Executive Officer:

If the Grants Administrator has determined that a financial conflict of interest exists, the Chief Executive Officer will develop a management plan that specifies the actions that have been and/or will be taken to manage the financial conflict of interest.

(1) In so doing, the Chief Executive Officer will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict.

(2) Management strategies may include, but are not limited to:

- (a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the financial conflict of interest;
- (d) Modification of the research plan;
- (e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- (g) Severance of relationships that create actual or potential financial conflicts.

(3) Specific Provisions Applicable to PHS-funded Research

In addition to the requirements of this policy outlined above, the Polisher Research Institute will apply the following specific provisions to research funded by PHS:

(a) Monitoring

For PHS-funded research, the INVESTIGATOR'S management plan will be monitored on an ongoing basis until the completion of the research project.

(b) Subrecipients

If the Polisher Research Institute carries out the PHS-funded research through a SUBRECIPIENT, the Polisher Research Institute will incorporate as part of a written agreement with the SUBRECIPIENT terms that establish whether the Polisher Research Institute's or the SUBRECIPIENT's policy on conflict of interest in research will apply to the SUBRECIPIENT Investigators.

If the SUBRECIPIENT's policy will apply, the SUBRECIPIENT will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the SUBRECIPIENT to report all identified financial conflicts of interest to the Polisher Research Institute to enable the Polisher Research Institute to provide timely reports to PHS.

Alternatively, if the Polisher Research Institute's policy on conflict of interest will apply, the agreement shall specify time period(s) for the SUBRECIPIENT to submit all SUBRECIPIENT Investigator disclosures of significant financial interests to the Polisher Research Institute. Such time periods shall be sufficient to enable the Polisher Research Institute to comply with timely review, management, and reporting obligations under the PHS regulations.

(c) Retrospective Review

In the event the Polisher Research Institute identifies a significant financial interest that was not disclosed in a timely manner by an INVESTIGATOR or, for whatever reason, was not previously reviewed by the Polisher Research Institute during an ongoing research project, and where the Grants Administrator has determined that the undisclosed significant financial interest constitutes a financial conflict of interest related to a PHS-funded research project, the Chief Executive Officer will review the financial conflict of interest and the Polisher Research Institute will implement a management plan for the project within 60 days of identification of that interest. In addition, the Chief Executive Officer will, within 120 days of their determination of noncompliance, complete a retrospective review of the INVESTIGATOR's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

(d) Mitigation Plan

If the Chief Executive Officer determines in the conduct of its retrospective review of PHS-funded research that the research or any part of it was biased, the Chief Executive Officer will recommend a mitigation plan to address any such issues. The Polisher Research Institute will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

(e) Public Access of Disclosed Significant Financial Interest

The Polisher Research Institute will make available to the public upon request information concerning any significant financial interest disclosed to the Polisher Research Institute that meets the following three criteria:

- (1) The disclosed significant financial interest is still held by the investigator or senior/key personnel of the active PHS project;
- (2) The Polisher Research Institute determines that the significant financial interest is related to the PHS-funded research; and
- (3) The Polisher Research Institute determines that the significant financial interest is a Financial Conflict of Interest.

The information request must be made to the Grants Administrator who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

(5) Ongoing Research

- (a) When in the course of an ongoing research project an INVESTIGATOR new to the project discloses a significant financial interest or an existing INVESTIGATOR discloses a new or changed significant financial interest, and where the Grants Administrator has determined that the disclosed significant financial interest constitutes a financial conflict of interest subject to management under this policy, the Chief Executive Officer will review the disclosure and the Polisher Research Institute will implement a management plan for the project within 60 days of the submission of the disclosure to the Polisher Research Institute.
- (b) In the case of either (a) or IV.4(c) above, and depending on the nature of the financial conflict of interest, the Polisher Research Institute may determine that additional interim measures are necessary with regard to the INVESTIGATOR's participation in the research project between the date of disclosure and the implementation of the Polisher Research Institute's management plan. Particular consideration will be given to any additional interim measures that the Polisher Research Institute's Institutional Review Board views as necessary for the protection of human participants in any ongoing research.

V. NON-COMPLIANCE

Alleged violations of this policy, by an INVESTIGATOR or SUBRECIPIENT, will be reviewed by means of an inquiry conducted by the Chief Executive Officer. Instances of deliberate breach of the policy, including failure to file; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed in fulfillment of this policy will be evaluated by the Chief Executive Officer. The Chief Executive Officer will determine the appropriate management plan, if any, to be imposed within 60 days of notification. Possible sanctions include: formal admonition; letter to the Investigator's personnel file; suspension of privileges to apply for external funds and/or seek IRB approval; or dismissal.

VI. REPORTING

The Polisher Research Institute will provide initial and ongoing reports of its management of financial conflicts of interest to external sponsors as required by law and in accordance with this policy.

If required by the funding agency's policy, the Polisher Research Institute will report the existence of related significant financial interest to the funding agency. PHS and funding agencies that have adopted the PHS requirement, require the reporting of the existence of a conflict of interest that is being managed prior to the expenditure of funds awarded.

VII. RECORDS

The Disclosure Form and records of all actions related to disclosure will be maintained by the Grant's Administrator for three years from the date the final expenditures report is submitted the PHS (NIH) of the relevant award, or any subsequent action relating to that award. All disclosures and related documentation are considered confidential, and only those persons involved in the implementation of this policy will have access to those records.

VIII. TRAVEL REIMBURSEMENTS AND SPONSORED TRAVEL

Each Investigator is responsible for disclosing the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). They are NOT required to disclose travel that is reimbursed or sponsored by:

- (1) a federal, state, or local government agency
- (2) an Institution of higher education as defined at 20 U.S.C. 1001(a)
- (3) an academic teaching hospital, a medical center
- (4) a research institute that is affiliated with an Institution of higher education

The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

IX. TRAINING

Each Investigator must complete FCOI training, located on NIH's web site (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>):

- (1) Prior to engaging in research related to any PHS-funded grant or contract
- (2) At least every four years,
- (3) Immediately under the designated circumstances:
 - (a) Institutional FCOI policies change in a manner that affects Investigator requirements
 - (b) An Investigator is new to an Institution
 - (c) An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

X. FEDERAL CONFLICT OF INTEREST REGULATIONS


NIH Public Health Service: <http://grants.nih.gov/grants/policy/coi/index.htm>

National Science Foundation: <http://nsf.gov/policies/conflicts.jsp>

Food and Drug Administration:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54&showFR=1>

Reviewed and Approved by:



Chief Financial Officer

8/20/12
Date