



**THE  
AMERICAN ACADEMY OF FAMILY PHYSICIANS  
POLICY FOR  
FINANCIAL CONFLICT OF INTEREST FOR RESEARCH**

**I. Introduction and Purpose**

The mission of the American Academy of Family Physicians (the “Academy”) is to improve the health of patients, families, and communities by serving the needs of its members with professionalism and creativity. One way the Academy strives to accomplish this is through the ongoing support, conduct, and dissemination of practice-based primary care research on matters of high relevance to family physicians and their patients.

The Academy has long been committed to having all aspects of its medical research conducted with the highest integrity and ethical standards. In order to preserve and protect the credibility of the Academy, this Policy for Financial Conflict of Interest for Research (this “Policy”) has been developed to comply with the requirements of 42 CFR Part 50, Subpart F, [\*Promoting Objectivity in Research\*](#), which is applicable to institutions that apply for Public Health Service (PHS) grants or cooperative agreements for research.

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 funded by PHS or other sponsors under grants, cooperative agreements, or contracts are susceptible to bias or favoritism related to the potentially conflicting financial interest(s) of an Investigator (defined below).

A potential financial conflict of interest occurs when there is a possibility, from the perspective of an independent observer, that an individual’s (or his/her spouse’s, domestic partner’s or dependent child’s) personal financial interests influence or *appear to influence* the ability of the individual to exercise objectivity or impair the individual’s ability to carry out his or her responsibilities in the best interests of the Academy. The Academy requires that all Investigators disclose any Significant Financial Interests (defined below).

**II. Definitions**

A. **Designated Academy Official.** The “*Designated Academy Official*” means one or more officials authorized by the Academy’s Executive Vice President or Deputy Executive Vice President, to solicit and review completed FCOI Disclosure Forms for Research Projects with responsibility for determining whether an Investigator has a Significant Financial Conflict of Interest.

- B. **FCOI Regulations.** “*FCOI Regulations*” mean 42 CFR Part 50, Subpart F, [Promoting Objectivity in Research](#), as amended from time to time.
- C. **Financial Conflict of Interest (“FCOI”).** A “*Financial Conflict of Interest*” is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- D. **Investigator.** “*Investigator*” means 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, including collaborators and outside consultants.
- E. **PHS.** “*PHS*” is the acronym used for 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, the Centers for Disease Control, the Health Resources & Services Administration, the Food & Drug Administration, Substance Abuse & Mental Health Services, Indian Health Services, the Agency for Toxic Substances & Disease Registry, the Agency for Health Care Research and Quality, and the Office of the Secretary.
- F. **Research.** “*Research*” means a systematic investigation, study or experiment designed to develop or contribute to general 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). The term includes any such activity for which research funding is available from PHS through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infra-structure award, institutional training grant, program project, or research resources award.

- G. **Significant Financial Interest.** A “*Significant Financial Interest*” means anything of monetary value to the Investigator (and those of the Investigator’s spouse, domestic partner and dependent children), including, but not limited to, the circumstances outlined below:
1. 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 of other reasonable measures of fair market value.

2. 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 and the value of any equity interest, when aggregated, exceeds \$5,000.
3. Intellectual property rights and interests (e.g., patents, copyrights and royalties from such rights), upon receipt of income related to such rights and interests.
4. Any reimbursed or sponsored travel paid by an outside entity. Exceptions include: travel reimbursements from an institution of higher education, a federal/state/local government, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher learning.

The term *Significant Financial Interest* does not include the following:

1. Salary, royalties, or other remuneration from the Academy;
2. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; or
3. Income from service on advisory committees or review panels for public or non-profit entities.

### **III. Training Requirements**

All Investigators must complete training for FCOI (i) prior to engaging in research related to any PHS-funded grant, (ii) at least every four years thereafter, and (iii) immediately when any of the following circumstances apply:

- this Policy changes in a manner that affects Investigator requirements;
- an Investigator is new to the Academy; or
- the Academy finds an Investigator noncompliant with this Policy or management plan.

Since research staff cycle on and off awards at varying times, the Academy requires all research staff to take FCOI training to ensure compliance and consistency. Training involves the Investigator being informed of this Policy, of the

Investigator's responsibilities regarding disclosure of Significant Financial Interests, and of the FCOI Regulations.

#### **IV. Disclosure, Review and Management**

Academy Division Directors are responsible for determining who in their area of responsibilities meets the definition of Investigator as set forth in this Policy and for ensuring that each Investigator has timely submitted an FCOI Disclosure Form for Research Projects.

Investigators must complete FCOI Disclosure Forms for Research Projects indicating whether they, including their spouses/domestic partners/dependent children, have a Significant Financial Interest.

##### Timing:

- New PHS-funded research: Each Investigator who is planning to participate in the PHS-funded research must complete an FCOI Disclosure Form for Research Projects no later than the time of application for PHS-funded research.
- Annually: During the period of the award, each Investigator must submit an updated FCOI Disclosure Form for Research Projects annually by August 31 of each year.
- Updates: Each Investigator must submit an updated FCOI Disclosure Form for Research Projects within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new Significant Financial Interest.

The Designated Academy Official will review the FCOI Disclosure Forms for Research Projects to determine whether an Investigator's Significant Financial Interest is related to PHS-funded research (a reasonable appearance that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research) and, if so related, whether the Significant Financial Interest is an FCOI (a reasonable determination that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

After reviewing the disclosure information, if the Designated Academy Official determines an FCOI exists, the Designated Academy Official will send a recommended management plan to the Investigator's Division Director, the Investigator's Vice President, and the Office of General Counsel as to how the FCOI will be managed, reduced, or eliminated. The following are examples of possible actions:

- Public disclosure (e.g., when presenting or publishing the research);
- Appointment of an independent reviewer to monitor the research;
- Modification of the research plan;
- Change personnel, change personnel's responsibilities, or disqualify personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest; and
- Severance of the relationship that creates the financial conflict(s).

## **V. Reporting Requirements**

Prior to committing or expending any funds under an award, the Academy must report to the PHS awarding agency any Investigator's FCOI (that has not yet been eliminated) and the implementation of a management plan.

The Academy must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds). Within 60 days of determining that an FCOI exists for a new Investigator who joins an ongoing PHS-funded research activity or there is a newly identified FCOI of an existing Investigator, the Academy must implement a management plan and submit a report to the PHS funding agency.

## **VI. Retrospective Reviews and Mitigation Reports**

If the Academy identifies a Significant Financial Interest during an ongoing PHS-funded research project that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Academy Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether an FCOI exists, and if so, implement a management plan on at least an interim basis.

In addition, whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined to be an FCOI, or the Academy did not review or manage the FCOI, or the Investigator failed to comply with a previously implemented management plan, the Academy must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. The Academy will document the retrospective review in accordance with the FCOI Regulations. Based on the results of the retrospective review, if appropriate, the previously submitted FCOI report should be updated to specify the actions that the Academy will take to manage the identified FCOI going forward.

If bias was found during the retrospective review, the Academy will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum

documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Academy's plans to eliminate or mitigate the effect of the bias.

## **VII. Disciplinary and Correction Action**

If the Designated Academy Official determines that an Investigator has failed to disclose an actual or possible Significant Financial Interest, the Designated Academy Official may do one or more of the following:

1. counsel the Investigator regarding his or her obligations under this Policy;
2. exclude the Investigator from future discussions on the matter at issue and any related matters; and/or
3. pursue another course action consistent with the Academy Bylaws and as may be approved by the Academy's Board of Directors.

## **VIII. Sub-recipient Requirements**

For any PHS-funded research in which the Academy is the awardee Institution, a written agreement is required to establish which institution's FCOI policy will apply to a sub-recipient institution and its Investigators. If the sub-recipient's policy applies, the agreement shall certify that the policy complies with 42 CFR Part 50 and 45 CFR Part 94. Otherwise the agreement shall state that the sub-recipient Investigators are subject to the Academy's FCOI Policy.

The agreement needs to specify timeframes for disclosing any Significant Financial Interest or FCOI to the Academy. Disclosed FCOIs shall be reported to PHS prior to the expenditure of any funds and within 60 days of any subsequently identified FCOI.

## **IX. Maintenance of Records**

The Academy shall maintain records related to all Investigator disclosures of financial interests and its review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under the Academy's policy for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other specified dates.



**FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM  
FOR RESEARCH PROJECTS**

Name of Investigator: \_\_\_\_\_

Name of Research Project: \_\_\_\_\_

Period:     Initial     Annual (August 31)     Updated Information

1. Within the last 12 months have you, your spouse, domestic partner and/or dependent children received any payments of any kind that, in the aggregate, exceed \$5,000 from any outside entity (publicly traded or non-publicly traded) that sponsors any of your AAFP research or whose interests or business might appear to be related to the above-named research project or other institutional responsibilities? *Exclude AAFP salary support received due to research agreements between the AAFP and a grantor/sponsor; income from authorship of scholarly works; and payments from a government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution affiliated with an institution of higher education for seminars, lectures, teaching engagements, advisory committees, or review panels.*

Yes     No

Do you expect to receive any such payments during the next 12 months?     Yes     No

2. Within the last 12 months have you, your spouse, domestic partner and/or dependent children owned or controlled any equity interests (e.g., stock and stock options, but excluding investments in mutual funds) in any outside entity (publicly-traded or non-publicly traded) that sponsors any of your AAFP research or whose interests or business might appear to be related to the above-named research project or other institutional responsibilities?

Yes     No

Do you expect this to occur during the next 12 months?     Yes     No

3. Within the last 12 months have you, your spouse, domestic partner and/or dependent children obtained any intellectual property rights (e.g., patents, patent applications, trademarks, copyrights, licenses, and/or royalties thereto) that are either related to any of your AAFP research or which might appear to be related to the above-named research project or other AAFP activities and responsibilities?

Yes     No

Do you expect this to occur during the next 12 months?     Yes     No

4. Within the last 12 months have you, your spouse, domestic partner and/or dependent children served as an officer, director, partner, manager or employee of an outside entity that sponsors any of your AAFP

research or whose interests or business might appear to be related to the above-named research project or other institutional responsibilities?

Yes       No

Do you expect this to occur during the next 12 months?     Yes       No

5. Within the past 12 months have you, your spouse, domestic partner and/or dependent children received any reimbursed or sponsored travel paid by an outside entity? *Exclude any travel reimbursements from an institution of higher education, a government agency, an academic teaching hospital, a medical center, or a research institution affiliated with an institution of higher education.*

Yes       No

Do you expect this to occur during the next 12 months?     Yes       No

6. If you answered "Yes" to any answer in questions 1-5, please complete the table below:

Name of Outside Entity	Type of Relationship/ Services Provided*	Who (Self, Family Member)	Approximate Dollar Amount

\* e.g., honoraria, stock ownership, intellectual property, advisory board.

You may add attachments for additional items or to further explain your responses.

**Certification**

I certify that (i) the above information is true and complete to the best of my knowledge, (ii) I have read the AAFP Policy for Financial Conflict of Interest for Research, (iii) I will promptly report to the AAFP any changes to the above information, and (iv) I will comply with any requests, conditions or restrictions imposed by the AAFP to manage actual or potential conflicts of interest.

I understand that unless disclosure is required under 42 CFR Part 50, Subpart F or other applicable federal law on reporting and public accessibility, only the Designated Academy Official, my Division Director, my Vice President, and the Office of General Counsel will have access to the information in this FCOI Disclosure Form for Research Projects and will retain it as confidential information.

\_\_\_\_\_

Date: \_\_\_\_\_

Signature