

# **American Academy of Pediatrics Policy/Reporting Form Financial Conflict of Interest for Research**

## **POLICY:**

### **Introduction**

The American Academy of Pediatrics' (AAP) policy on Financial Conflict of Interest for Research Projects policy is developed to comply with regulations issued in 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought ([http://grants.nih.gov/grants/compliance/42\\_CFR\\_50\\_Subpart\\_F.htm](http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)). This subpart is applicable to each institution that applies for Public Health Service (PHS) grants or cooperative agreements for research.

The purpose of these regulations 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 these sponsors under grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an investigator. These guidelines define AAP policy and procedures regarding conflicts of interest in relation to sponsored research projects.

A potential conflict of interest exists when an individual's personal interests might lead an independent observer to reasonably question whether the individual's professional actions are determined by significant personal interest. In accordance with federal regulations, the goal of the AAP's system is to ensure that the personal interests of an individual do not unduly influence their work on a sponsored project. The AAP requires that all investigators (see definition of investigator below) disclose any significant financial interests. This policy applies to all investigators and includes project consultants.

### **Definitions**

#### **A. 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, or proposed for such funding, including collaborators and consultants. The AAP further interprets the term "investigator" to include all staff and consultants who have meaningful input into the program, as well as principal investigators on AAP awards, irrespective of home institution.

## **B. Significant Financial Interest**

Significant financial interest means anything of monetary value to the investigator that reasonably appears related to the investigator's institutional responsibilities, including, but not limited to, the circumstances outlined below. The definition includes the financial interests of the investigator's spouse and dependent children.

- 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.
- 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 investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 education.

The term does not include the following:

1. Salary or other remuneration from the AAP.
2. Income from lectures, or teaching engagements sponsored by 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.
3. Income from service on advisory committees or review panels for 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.

## **Reporting Requirements**

Each investigator must complete an annual AAP Financial Conflict of Interest Reporting Form for Research Projects in which they indicate whether or not they, including their spouse/domestic partner and dependent children, may have a significant financial interest: (1) that would reasonably appear to be affected by the research for which funding is sought; and (2) in entities whose financial interests would reasonably appear to be related to their AAP institutional responsibilities.

Prior to the submission of an application for a PHS grant, each investigator taking part in the

project to be funded by that grant must review his or her current reporting status with respect to significant financial interests, updating it if necessary, and he or she must identify any such interests that could potentially give rise to a conflict related to the project to be funded. Any such interests (whether previously reported or not) must be specifically reported to the AAP Executive Director's Conflict of Interest Management Advisory Committee (COIMAC) and any such report shall include a description of the circumstances under which any such interests could potentially give rise to a conflict with respect to the project.

AAP Department Directors/Executive Staff 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 submitted a form.

Prior to committing or expending any funds under an award, the AAP must assess whether or not to report to the appropriate federal agency the existence of any conflicting financial interests. If there is a financial conflict of interest, the AAP must, also, prior to committing or expending any funds under an award, assure that the interest has been managed, reduced or eliminated in accordance with the regulation.

### **Subsequent Identification and Reporting**

All financial disclosures must be updated during the period of the award if the individual has a change in status regarding reportable conflicts and if new investigators are added to the project.

Timing:

- Annually: The AAP Financial Conflict of Interest form must be completed annually and submitted by August 31<sup>st</sup> each year.
- Upon appointment/hire: New relevant hires must complete and submit the form within 30 days of joining the AAP.
- Updates: The AAP Financial Conflict of Interest form must be updated and resubmitted when there is a relevant change in activities or financial interests within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance).

### **Review of the Potential Financial Conflict of Interest Disclosure**

If an investigator discloses a significant financial interest, the AAP Executive Director's Conflict of Interest Management Advisory Committee (COIMAC) will provide initial review of the disclosure and may request additional supporting documentation from the investigator. COIMAC will review the disclosure of the financial interest to determine whether the financial interest relates to PHS-funded research and whether the financial interest which has been disclosed amounts to a financial conflict of interest. A financial conflict of interest exists when it is reasonably determined that a significant financial interest could directly and significantly affect the design, conduct or reporting of PHS-funded research. After reviewing the financial disclosure, COIMAC will make a recommendation to the AAP Executive Director as to whether a financial conflict of interest exists, and if a financial conflict of interest does exist, how it can be managed, reduced, or eliminated.

The following are examples of possible actions that could be taken to manage, reduce or eliminate a financial conflict of interest:

- (1) Public disclosure of significant financial interests;

- (2) Monitoring of research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in all or a portion of the research funded by the PHS;
- (5) Divestiture of significant financial interests; or
- (6) Severance of relationships that create actual or potential conflicts

## Compliance

All persons subject to this policy are expected to comply with it fully. The AAP will follow all policies as outlined in 42 CFR Part 50, Subpart F related to training requirements, disclosure, management, reporting requirements, public accessibility, and retrospective review and mitigation. In the event a conflict of interest is identified, the AAP is required to report to the PHS awarding component the conflict of interest as well as corrective action taken or to be taken.

## Record Retention Policy

The AAP is required pursuant to 42 CFR Part 50, Subpart F to maintain all conflict of interest disclosure forms and related communications with investigators and all actions taken for a period of three years from the date of submission of the final expenditures report or, where applicable, from other dates specified.

For further information about federal requirements related to research and financial conflict of interest (FCOI):

- The National Institutes of Health (NIH) has a web site on FCOI: <http://grants.nih.gov/grants/policy/coi/>.
- Relevant AAP investigators are required to obtain training on FCOI through the Collaborative Institutional Training Initiative (CITI).

# AMERICAN ACADEMY OF PEDIATRICS FINANCIAL CONFLICT OF INTEREST REPORTING FORM FOR RESEARCH

Name: \_\_\_\_\_

Title \_\_\_\_\_

Department: \_\_\_\_\_

Period:  Annual (20\_ \_ ) Beginning August 31  Updated Information

## PART I: GENERAL QUESTIONS

Definitions:

- Human subjects research includes obtaining data or specimens identifiable to living individuals for research purposes
- Investigator - person who is responsible for the design, conduct, or reporting of research
- Family members – spouse, domestic partner, dependent children
- Financial interest – anything of monetary value, including: salary or other payments for services (e.g. consulting fees, payment for educational lectures, expert witness payments and honoraria); equity interests (e.g. stock or other ownership interests, but not investments in mutual funds); and intellectual property rights (e.g. patents, trademarks, service marks, copyrights, and royalties).

RESPOND TO THE FOLLOWING QUESTIONS IF YOU CONDUCT HUMAN SUBJECTS RESEARCH AS AN INVESTIGATOR AT OR ON BEHALF OF THE AAP.

- 1a. In the past 12 months, did you or any of your family members receive any payments (such as salary, consulting fees, speakers fees or honoraria) that, in the aggregate, **exceed \$5,000** from any outside entity (publicly traded or non-publicly traded) that sponsors any of your AAP research, or whose interests or business are related to your AAP research or other institutional responsibilities? *Exclude AAP salary support received due to research agreements between the AAP and the 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.*

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect to receive any such payments during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

- 1b. In the past 12 months, did you or your family members own or control any equity interests (such as stock, stock options or other ownership interests, but excluding investments in mutual funds) valued at **\$5,000 or more** in any publicly-traded outside entity that sponsors any of your AAP research, or whose interests or business are related to your AAP research or other institutional responsibilities?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

- 1c. In the past 12 months, did you or your family members own or control any equity interests (such as stock, stock options or other ownership interests, but excluding investments in mutual funds) in a non-publicly-traded outside entity that sponsors any of your AAP research, or whose interests or business are related to your AAP research or other institutional responsibilities?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

2. In the past 12 months, did you or your family members have, or expect to have, any intellectual property rights, such as patents, patent applications, trademarks, servicemarks, copyrights, licenses and/or royalties, which are either related to your AAP research activities, or which might be considered related to other AAP activities and responsibilities?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

3. In the past 12 months, did you or any of your family members serve as an officer, director, partner, manager or employee of an outside entity that sponsors any of your AAP research, or whose interests or business are related to your AAP research or other institutional responsibilities?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

4. In the past 12 months, did you or any of your family members receive any reimbursed or sponsored travel paid by an outside entity? *Do not 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 education. If yes, specify the purpose of the trip, the identity of the sponsor / organizer, the destination and the duration.*

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

**ALL RESPONSES WILL BE MAINTAINED ON A CONFIDENTIAL BASIS, EXCEPT TO THE EXTENT REQUIRED TO BE DISCLOSED TO THE PHS AWARDING COMPONENT CONSISTENT WITH 42 C.F.R. Part 50, Subpart E.**

**PART II: FINANCIAL RELATIONSHIPS WITH RESEARCH ACTIVITIES**

If you have a financial interest that resulted in a yes answer to questions 1-4 please complete this section. Do not list salary support or similar payments received under AAP sponsored research agreements.

Name of Company or Sponsor	Type of relationship and services provided*	Who	Approximate amount of payments/ value of equity interest	Managerial/ Board role? (if so, list role)
		<input type="checkbox"/> self <input type="checkbox"/> family member**		
		<input type="checkbox"/> self <input type="checkbox"/> family member** <input type="checkbox"/> member**		
		self <input type="checkbox"/> family member** <input type="checkbox"/> member**		
		self <input type="checkbox"/> family member** <input type="checkbox"/> member**		
		self family member**		

\*E.g. stock ownership, consulting, intellectual property; speaker's bureau, advisory board, educational grants. Do not list AAP research funding.

\*\*If family member, are they an AAP employee? \_\_\_\_ If so, please name: \_\_\_\_\_

- You may add attachments for further explanation of your responses.

### **PART III: CERTIFICATION AND SIGNATURE**

#### **Certification:**

I certify that (a) the above information is true and complete to the best of my knowledge, (b) I have read the AAP Policy on Financial Conflict of Interest for Research Projects, and (c) I am in compliance with AAP policy on this matter. I will comply with any conditions or restrictions imposed by the AAP to manage actual or potential conflicts of interest.

I agree to update and submit this Conflict Reporting Form when my financial interests or relationships with outside entities, or those of my family members, change in a way that changes the answers above.

If I do have a significant financial interest, I agree to attach supporting documentation (in an envelope marked "confidential") that identifies and describes the financial interest involved. Unless disclosure is required under 42 C.F.R. Part 50, Subpart F or other federal law on reporting and public accessibility, only the respective Department Director and the Executive Director's Conflict of Interest Management Advisory Committee (COIMAC) will have access to this information and will retain it as confidential information.

Signature:

\_\_\_\_\_  
Investigator Signature

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

\_\_\_\_\_  
Department Director Signature

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

Department Director to Check One:

- No Conflicts Identified
- Potential Conflict Identified (Department Director must forward to COIMAC for review)

Document Retention:

Each AAP Department Director will maintain a log of who in their areas has signed this FCOI form and will retain signed copies in a locked location in their department.