



**Academic Pediatric Association  
Financial Conflict of Interest (FCOI) Policy**

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## Purpose of FCOI

This FCOI establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Effective interactions between research institutions, government, the private sector, and industry are essential to bring about the rapid application of scientific discoveries to address the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships, now encouraged in many forms, are increasingly complex, and may involve financial interests that give rise to a Financial Conflict of Interest (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of an Investigator's research in return for a financial benefit to the Investigator or his/her/their immediate family.

In addition, a Conflict of Commitment can arise if an Investigator's efforts for the APA are diminished by commitments to outside activities and commitments. APA's Investigators' primary commitment of time and intellectual energies should be to APA's research, education, policy and advocacy, and healthcare delivery programs. Consistent with the foregoing, many U.S. federal agencies, including the National Institutes of Health (NIH) and National Science Foundation (NSF), require that their supported Investigators adequately disclose and report all of their outside professional activities, affiliations and appointments, whether or not compensated, and identify all resources made available in support of their research endeavors.

A Financial Conflict of Interest or a Conflict of Commitment may arise even though no improper conduct or unethical behavior has occurred. The APA and its Investigators are responsible for identifying and then managing these Financial Conflict of Interests and Conflicts of Commitment to strengthen accountability and transparency, promote research objectivity, and maintain the integrity of research findings and prudent stewardship of public funds. The APA's Investigator Financial Conflict of Interest Policy was developed to comply with the specific federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts). Section 20, *Additional Resources*, includes links to the federal regulations. The U.S. Public Health Service (PHS) oversees and monitors the APA's compliance with these regulations. PHS may inquire at any time before, during, or after a sponsored research award about an Investigator's Significant Financial Interest or external activity, and the APA's review and response to such disclosure, regardless of whether the disclosure resulted in the APA finding a FCOI.

All APA Investigators are responsible for familiarizing themselves with the aforementioned regulations so the APA can effectively work with them to comply with these federal disclosure requirements. In turn, all Investigators will be notified about the APA's conflict of interest requirements, as well as their disclosure responsibilities under this Investigator Financial Conflict of Interest Policy.

The APA's Board of Directors and Research and Grants Manager administer this Policy and emphasize compliance with its requirements, including the review of Annual Disclosure Forms, the training and management of Investigators with regard to Financial Conflict of Interest and Conflict of Commitment requirements, and the timely identification, reporting and management of FCOIs. In those instances where a funding agency or sponsor has more stringent requirements and regulations relating to conflict of interest or conflict of commitment than those in the APA's Investigator Financial Conflict of Interest Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

### Applicability of FCOI

This FCOI Policy is applicable to each Institution or Individual that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement in collaboration with the Academic Pediatric Association (APA), and to each Investigator who is planning to participate in, or is participating

in, the design, conduct, and reporting of research carried out for the APA as well as any others deemed appropriate by the APA Board of Directors.

### Mandated Conflict of Interest Training for All Investigators

All Investigators who are subject to the Investigator FCOI Policy are mandated to complete the online, Investigator Conflict of Interest Training Tutorial prior to engaging in research for or on behalf of the APA, and at least every four years thereafter or immediately if (1) an Investigator is new to the APA; (2) the APA's Investigator FCOI Policy changes in a manner affecting Investigator requirements; or (3) the APA finds that an Investigator is non-compliant with the APA's Investigator FCOI Policy or an applicable management plan.

Subrecipient Investigators who are subject to the APA's Investigator FCOI Policy and participate in PHS-funded research are also required to complete the Investigator FCOI Training Tutorial.

Investigator training completion dates are monitored by the APA's Research and Grants Manager.

### What Should be Disclosed?

Each of the following Significant Financial Interests and Outside Activities and Interests should be disclosed on the Annual Disclosure Form and described on an Appendix Form to the extent they reasonably appear to be related to the Investigator's Institutional Responsibilities. In the interest of full transparency, Investigators should err on the side of disclosure.

1. With regard to any publicly traded entity, domestic or foreign, the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest held in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000.
  - a. Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria and paid authorship.
  - b. Equity interests include stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.

**Note:** Disclosure is not required for income from investment vehicles, such as mutual funds, ETFs, and retirement accounts as long as the Investigator does not directly control the investment decisions made in these vehicles.

2. With regard to any non-publicly traded entity, domestic or foreign, (a) the value of any remuneration received from the entity in the 12 months preceding the disclosure that when aggregated exceeds \$5,000, and (b) any equity interests in the entity (regardless of value) that are held by the Investigator or his/her spouse or domestic partner or dependent children.
  - a. Equity interests include stocks, stock options, or other ownership interests.
  - b. If at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity, the Investigator must fully

describe the nature of the equity interest, including the number of shares owned, voting rights, etc.

3. Financial interests received in connection with patents, copyrights, know-how or other intellectual property rights (e.g., royalties, license fees, equity or other consideration) that when aggregated over the prior 12 months exceeds \$5,000, including consideration received pursuant to an agreement to share royalties related to such intellectual property rights.

**Note:** Disclosure is not required for royalties, fees or other consideration paid to the Investigator by the APA for intellectual property owned by the APA (i.e., not personally owned by the investigator).

4. Any advisory relationship, consulting, outside teaching, or scientific/academic appointment including adjunct, visiting or honorary, with any domestic entity (other than the APA), both paid and volunteer, as well as any unpaid appointment that provides the Investigator with access to, or in-kind support for, laboratory space, research materials, supplies, equipment, staff participation or living expenses.

**Note:** Disclosure is not required for the following:

- a. Salary or other remuneration received from the APA if the Investigator is currently employed or appointed by the APA.
  - b. Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
  - c. Income from service on advisory committees or review panels for a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
5. Any relationship with a foreign entity or government including, but not limited to, any involvement with a government talent recruitment program or similar-type program, both paid and volunteer, and any position or scientific appointment stemming from a foreign government, which includes local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.
  6. All reimbursed expenses, gifts, gratuities, favors, lodging, or entertainment offers that when aggregated over the prior 12 months exceeds \$1,000. As a reminder, Investigators may not solicit or accept reimbursed expenses, gifts, gratuities, favors, lodging, or excessive entertainment for themselves, his/her spouse or domestic partner or dependent children, alone or in combination, or for any person or organization that does business or has the potential of doing business with the APA. Exempt from this prohibition are non-cash gifts of nominal value involving normal and ordinary social amenities or sales promotions.

## 7. Disclosure of Sponsored/Reimbursed Travel

What travel must be disclosed?

- a. Disclose travel within the United States received from a U.S. entity that when aggregated exceeds \$5,000.

**Note:** Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- b. Disclose travel outside the United States received from a U.S. or foreign entity\* regardless of dollar amount.

\*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

What information is needed for the Disclosure?

- a. The identity of the sponsor/organizer.
- b. The month and year of the travel.
- c. The financial value by range of the travel.
- d. The value of any associated honorarium.
- e. The purpose of the travel.
- f. The destination of the travel.
- g. The time duration of the travel.

**Note:** Most scientific journals have implemented policies requiring authors to declare competing financial interests in relation to work published in those journals. Such requirements, including how financial interests are defined under those policies, are distinct from federal requirements relating to federally funded research and should not be used as a guide to what information an Investigator needs to disclose under the APA's Investigator FCOI Policy.

### Who Must Submit an Annual Disclosure Form?

Institutions or Individuals applying for, or receiving, PHS research funding by means of a grant or cooperative agreement in collaboration with the Academic Pediatric Association (APA), and each Investigator who is planning to participate in, or is participating in, the design, conduct, and reporting of research carried out for the APA as well as any others deemed appropriate by the APA Board of Directors must complete an Annual Disclosure Form at the beginning of their association with the APA and each subsequent year thereafter.

Submitted Annual Disclosure Forms are retained in APA records.

## Updating the Annual Disclosure Form

All Investigators are required to simultaneously submit a current, accurate Annual Disclosure Form that identifies and describes both existing and new Significant Financial Interests and Outside Activities and Interests that reasonably appear to be related to their Institutional Responsibilities. Subrecipient Investigators will complete an Annual Disclosure Form based on their funding cycle. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

Investigators are required to promptly disclose Significant Financial Interests and Outside Activities and Interests to accurately reflect their external activities as follows:

1. Disclose Significant Financial Interests and Outside Activities and Interests no later than at the time of application for PHS-funded research.
2. Within 30 days of acquiring and/or discovering a new Significant Financial Interest or Outside Activity or Interest, including through purchase, marriage, or inheritance.
3. Within 30 days of a material change to a previously disclosed Significant Financial Interest or Outside Activity or Interest.
4. At least annually within 45 days of the start of a new project period that has been set forth by the Notice of Award (NOA) or other agreement.

## Annual Disclosure Form Reviewed by the APA Board of Directors

The APA's Research and Grants Manager will review the Annual Disclosure Form and any new or modified Significant Financial Interests or Outside Activities or Interests disclosed throughout the year, and as such, may request further information or clarification from Investigators. The APA's Research and Grants Manager will review each Investigator's disclosures and determine whether a Significant Financial Interest or Outside Activity or Interest is related to PHS funded research.

If there are Significant Financial Interests or Outside Activities or Interests related to any Investigator's funded research, these relationships must be examined and dealt with according to the APA and funding agency policies on conflict of interest. A personal financial interest with an entity would be reasonably considered related to an Investigator's research in circumstances such as the following:

1. Entity sponsors research at the APA in which an Investigator is directly involved.
2. Entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of an Investigator's research.
3. Entity has a reasonable possibility of being financially affected by an Investigator's research.
4. Entity makes monetary or in-kind gifts or loans to the APA that benefit an Investigator's research including a gift or loan of equipment.
5. Entity makes a product that is under study in research in which an Investigator is involved.

6. Entity licenses intellectual property from the APA in which an Investigator has a financial interest.
7. Entity has a Material Transfer Agreement to provide materials used in an Investigator's research or for materials provided by an Investigator to the entity.
8. Entity sponsors or makes a product that is under study in human subjects in which an Investigator is directly or indirectly involved.

The APA's Board of Directors reviews all Significant Financial Interests and Outside Activities and Interests to identify and address any issues.

A FCOI will be deemed to exist when the APA, acting through its Board of Directors and following the procedures described in this Investigator FCOI Policy, reasonably determines that a Significant Financial Interest or Outside Activities and Interests could directly and significantly affect the design, conduct or reporting of an Investigator's research. The APA's Board of Directors reviews and analyzes the specific circumstances of a Significant Financial Interest by taking into account such factors as the nature of an Investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and an Investigator's research. The APA's Board of Directors may, if warranted, involve an Investigator in determining whether a Significant Financial Interest is related to the research in question.

### Managing a Financial Conflict of Interest

If a Significant Financial Interest is identified as a FCOI, the APA's Board of Directors will take action to manage the FCOI by robustly reducing or eliminating the conflict by designing a management plan or mechanism appropriate for the specific situation. During the design process, the APA's Board of Directors may query any Offices of Sponsored Programs, Internal Review Boards, or any APA Committees or task forces, departments or individuals as necessary to solicit additional information and alternate ideas. The APA's Board of Directors will, as necessary, accept, modify or reject the proposed management plan. After the management plan is approved by the APA's Board of Directors, the Research and Grants Manager will forward a detailed letter to the Investigator describing the management plan and its implementation.

This written plan will require that the Investigator take certain steps according to guidelines approved by the APA Board of Directors. Conditions or restrictions that might be imposed to manage a FCOI include the following:

- Disclosure of the FCOI to lab personnel and collaborators.
- Disclosure of the FCOI directly to human subject research participants.
- Disclosure of the FCOI in publications, journals, and posters, etc.
- Disclosure of the FCOI to audiences at conferences, seminars, and other public presentations.
- Monitoring of research, proposals and data by independent peer reviewers.
- Modification of the research plan.
- Removal of an affected Investigator from participation in all or the portion of the research funded by the entity affected by a Significant Financial Interest.
- Divestiture of a Significant Financial Interest by the affected Investigator.

- Limiting the dollar value of fees received and/or stock ownership.
- Severance of the relationship creating the conflict.

The Investigator will be asked to review and sign the letter to acknowledge agreement with the management plan, or the Investigator may, at this point, appeal the findings of the APA Board of Directors to the APA President by forwarding a written request for reconsideration of these findings to the APA President within 30 days. The APA President will determine whether the FCOI exists and the appropriate plan for managing the FCOI. The APA President has the final review and authority regarding the management of all FCOIs.

### Reporting a Financial Conflict of Interest to the Funding Agency

The APA will promptly notify the appropriate funding agency about any corrective action taken or to be taken in a situation of noncompliance.

1. Regarding a new NIH-sponsored research award, the APA will report the identified FCOI to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. The APA will submit the FCOI report before dispensing or spending any funds. If the FCOI is eliminated prior to dispensing or spending any funds, then no FCOI report is required. In addition, the APA is required to submit a FCOI report for FCOIs identified for subrecipient Investigators, if applicable. Refer to *Subrecipient Conflict of Interest Compliance*, for more information regarding subrecipients.
2. Regarding an ongoing NIH -sponsored research award, the APA will report to the NIH through the eRA Commons FCOI Module information about the identified FCOI within 60 days of the FCOI's identification. For any Significant Financial Interest that is identified as a FCOI subsequent to the APA's initial FCOI report during an ongoing NIH-funded research project, the APA shall, within 60 days, review the Significant Financial Interest disclosure, determine whether it is related to the research, and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage the FCOI.
3. Annual FCOI follow-up reports will be provided to the NIH for any FCOI previously reported by the APA. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the management plan or explain why the FCOI no longer exists. The APA will provide annual FCOI reports for the duration of the project period, including extensions with or without funds, as prompted by the eRA Commons-generated email that requests that the follow-up report be submitted.
4. The APA will meet the reporting requirements pertaining to FCOIs for other federally funded agencies, including DOD, DOE, NSF and USDA as instructed by the particular agency.
5. Regarding a new, non-federally funded award, the APA may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational institution, non-profit entity, private foundation, trust, and individual donor before dispensing or spending any funds.
6. Regarding an ongoing, non-federally funded award, the APA may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational



institution, non-profit entity, private foundation, trust, and individual donor during the award's duration.

## What Information is Submitted to the NIH About a Financial Conflict of Interest?

Information submitted to the NIH about an identified FCOI includes the following:

- Project number/contract number.
- Name of the Principal Investigator or Project Director, or the contact PI/PD if a multiple PI/PD model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has the FCOI.
- Statement about how the FCOI was managed.
- The nature of the FCOI (e.g., equity interest, consulting fees, intellectual property rights and interests, travel reimbursement, and/or honoraria).
- The value of the financial interest; \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.
- A description about how the FCOI relates to the research and the basis for the APA's determination that a Significant Financial Interest conflicts with such research.

A description of the key elements of the APA's management plan must also be submitted to the NIH, including the following information:

- Role and principal duties of the conflicted Investigator in the research project.
- Conditions of the management plan.
- How the management plan is designed to safeguard objectivity in the research project.
- Confirmation of the Investigator's agreement to the management plan.
- How the management plan will be monitored to facilitate Investigator compliance.
- Other information as needed.

Other funding agencies outside the NIH may require different information to be submitted, and the APA will meet their requirements as instructed.

## Public Accessibility to the APA's Investigator Financial Conflict of Interest Policy and Identified Financial Conflicts of Interest

The APA's Investigator FCOI Policy is publicly accessible on its [website](#).

The APA maintains public accessibility to Significant Financial Interests of senior/key personnel that were identified as FCOIs and reported to the NIH. As such, the APA responds to all written requests for information within five business days and then releases the following information about such Significant Financial Interest.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.

- Name of the entity with which the Significant Financial Interest is held.
- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by the dollar range \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

### Continued Monitoring of a Financial Conflict of Interest and APA Compliance

The APA continually monitors the FCOI and Investigator compliance with the FCOI management plan throughout the year and until the completion of the research project. As necessary, the APA Board of Directors may require and develop a project-specific monitoring process, which may include appointing an APA-designated official to assist with monitoring the FCOI and Investigator compliance.

### What Happens After the FCOI is Reported to the NIH (or Other Agencies)?

The NIH evaluates the FCOI information received through the eRA Commons FCOI Module to determine if the APA's actions are sufficient to manage the identified FCOI. The NIH may request and review additional information before implementing, if needed, further corrective actions to ensure research objectivity. If the NIH decides that the particular FCOI will bias the objectivity of the funded research to such an extent that further corrective action is needed or that the APA has not managed the FCOI in accordance with the regulation, it may impose special award conditions, suspend the funding or enforce other actions until the matter is sufficiently resolved.

Other funding agencies outside the NIH may have a different process, and the APA will meet their requirements as instructed.

### Non-Compliance and Enforcement

The APA will establish adequate enforcement mechanisms, provide for employee sanctions and take other administrative action, where appropriate, in the event an Investigator is non-compliant with the Investigator FCOI Policy or management plan. Violations of this Policy may be grounds for progressive disciplinary action including:

1. Placing a hold on the processing of new sponsored research applications from a non-compliant Investigator.
2. Withholding disbursement or distribution of project-specific funding to the Investigator's laboratory, research team, or other associated facilities and groups.
3. Suspension or termination of APA membership.

An Investigator is non-compliant and in violation of the Policy if an Investigator fails to:

1. Submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions by the APA Board of Directors.
2. Provide the APA Board of Directors with written acknowledgement of a management plan.

3. Provide the APA Board of Directors with requested documentation regarding compliance with a management plan.

If an Investigator fails to comply with the APA's Investigator FCOI Policy or management plan, within 120 days the APA will:

1. Complete a retrospective review of the key elements (see below) of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct, or reporting of research.
2. Document the retrospective review.
3. Document the APA's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Investigator FCOI Policy or management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, the APA will submit a mitigation report with the key elements (see below) addressing the impact of the bias on the research project, including the extent of the harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions the APA has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, the APA may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date the FCOI is identified and the completion of the APA's retrospective review. Thereafter, the APA will submit FCOI reports as prescribed by the regulation.

Furthermore, if the NIH determines that one of its funded clinical research projects 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 APA, the APA shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

The following key elements apply to both the retrospective review and mitigation report:

- Project number.
- Project title.
- The PI or contact PI/PD, if a multiple PI model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has a FCOI.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review including the methodology of the process, composition of the review panel, documents reviewed etc.
- Findings of the review.
- Conclusions of the review.

## Project-Specific Disclosure Form Submission

The Principal Investigator or Project Director involved with a funding submission is required to complete a Project-Specific Disclosure Form one week prior to submitting a sponsored research application requesting an amount greater than \$5,000 from a corporation, educational institution, federally funded agency, non-profit entity, private foundation or trust in order to confirm the PI/PD's compliance with the Investigator FCOI Policy.

The basic information needed to complete the Project Specific Disclosure Form is as follows:

- Name of the Principal Investigator or Project Director.
- Name of the funding organization.
- The funding opportunity announcement.
- Submission deadline.
- Project title.
- Names of personnel who are responsible for the design, conduct or reporting on any of the proposed research, including non-APA Investigators (domestic and foreign) such as collaborators, sub-recipients, or subcontractors proposed for funding.
- Any scientific element or segment of the project that is being conducted outside of the U.S., regardless of whether the foreign component will receive funding from the sponsored research application.
- If a foreign component provides the Principal Investigator or Project Director or any of their research team members with any resources or financial support, access to, or in-kind support for laboratory space, research materials, supplies, equipment or staff participation.

The Project-Specific Disclosure Form then confirms the following:

- That the Principal Investigator or Project Director has read the Investigator FCOI Policy and submitted an Annual Disclosure Form in the last 12 months.
- That the Principal Investigator or Project Director does not have any new or changed Significant Financial Interest information to disclose.
- Whether any Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.
- The project's involvement in a clinical trial.
- The involvement of any foreign component.

The APA Research and Grants Manager will contact any Principal Investigator or Project Director who fails to submit a Project-Specific Disclosure Form. Upon receipt of an award notice of \$5,000 or more, the APA Research and Grants Manager will verify that a Project-Specific Disclosure Form was received, and if not, the Principal Investigator or Project Director must complete the Project-Specific Disclosure Form for the award to be processed by the APA.

## Foreign Research Components

The APA values international collaborations, but the U.S. federal government remains concerned about foreign threats to the research infrastructure in the U.S. As such, APA Principal Investigators or Project Directors are asked to disclose on the Project-Specific Certification Form any scientific element or segment of the project that is being conducted outside of the U.S., regardless of whether the foreign

component will receive funding from the sponsored research application. In addition, the Principal Investigator or Project Director is asked to disclose if a foreign component provides the Principal Investigator or Project Director or any of their research team members with any resources or financial support, access to, or in-kind support for laboratory space, research materials, supplies, equipment or staff participation. The APA Board of Directors and/or federal funding agencies may request additional information regarding a foreign research component, and if needed, institute specific corrective actions to comply with the NIH Grants Policy statement. Refer to *Additional Resources*, for a link to the federal regulation.

Activities that meet the definition of a foreign component include, but are not limited to the following:

- The involvement of human subjects or animals from or in a foreign entity.
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities.
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
- Collaborations with Investigators at a foreign site anticipated to result in co-authorship.
- Use of facilities or instrumentation at a foreign site.
- Receipt of financial support or resources from a foreign entity.

**Note:** Foreign travel for consultation is not considered a foreign component but requires disclosure as Sponsored/Reimbursed Travel. Refer to *What Should be Disclosed* for more information about foreign travel disclosure.

### Subrecipient Conflict of Interest Compliance

A subrecipient relationship is established when federal funds flow down from or through the APA to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to the APA for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to the APA's terms and conditions, and as such, the APA will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. The APA will incorporate, as part of a written agreement with the subrecipient, terms that establish whether the APA's Investigator FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with the APA that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to the APA's Investigator FCOI Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the APA. The APA will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to the APA. Such time

period must be sufficient to enable the APA to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to the APA's Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the APA. Such time period shall be sufficient to enable the APA to comply with its review, management, and reporting obligations under the regulation. The APA will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

Other funding agencies outside the PHS may have a different process as it pertains to subrecipients, and the APA will meet their requirements as instructed.

## Record Retention

Records relating to conflict of interest matters covered under this Investigator FCOI Policy for PHS-funded research must be maintained for a minimum of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. Records for conflict of interest matters relating to other funded research will be maintained in accordance with the APA's Record Retention Policy.

## Additional Resources and PHS Policy Links

Please contact the APA's Research and Grants Manager by email at [info@academicpeds.org](mailto:info@academicpeds.org) to inquire about the Investigator FCOI Policy or about the APA's compliance.

- See the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) ([click this link to access the regulation](#)) and 45 CFR Part 94 (contracts) ([click this link to access the regulation](#)).
- See the NIH's Office of Extramural Research Financial Conflict of Interest Webpage ([click this link to access the Web page](#)).
- See the NIH's training about FCOIs:
  - [Financial Conflict of Interest Presentation with Case Studies](#) (06/26/2012) - (PowerPoint - 13.4 MB) - These slides provide an overview of the Federal FCOI regulation provided at [42 CFR Part 50, Subpart F](#) on *Promoting Objectivity in Research* that was presented at the NIH Regional Seminar in Washington, DC on June 22, 2012.
  - [What NIH Grantees Need to Know About the 2011 Revised Financial Conflict of Interest Regulation:](#)  
*Webinar, November 30, 2011, 2-3:30pm EST.*
    - [Archive](#)
    - [FCOI Webinar PowerPoint Slides](#) (PowerPoint - 7.3 MB)
    - [FCOI Webinar PowerPoint Slides](#) (PDF - 2.5 MB)
- See the Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components ([click this link to access the Web page](#)) to determine if additional disclosures should be made.

## Definitions

1. A *clinical trial* is a prospective or behavioral research study of human subjects that involves one or more Investigators who directly observe a person or people, and/or who collect data to

answer a scientific or medical question about the safety or potential benefit of an intervention such as medication, device, teaching concept, training method or behavioral change.

2. *Conflict of Commitment* refers to situations in which an Investigator is dedicating time to Outside Activities or Interests that may detract from the Investigator's primary responsibility to the APA. The issue regarding Conflicts of Commitment is not necessarily financial or potential bias in judgment, but rather whether an Investigator's commitment of time and effort are inconsistent with his/her/their obligations and commitment to the APA and its interests.
3. *Disclosure of significant financial interests* means an Investigator's disclosure of significant financial interests to an Institution.
4. *FCOI report* means an Institution's report of a financial conflict of interest to a PHS Awarding Component affected by the FCOI. In the case of NIH funding, a report about the identified FCOI will be entered into the eRA Commons FCOI Module. Other funding agencies may have separate reporting requirements, and these will be met as required.
5. *Federally funded research or PHS-funded research* means any research funded by the Public Health Service (PHS) 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). Other federal agencies include the National Science Foundation (NSF), Department of Defense (DOD), and Department of Energy (DOE).
6. *Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
7. *Foreign component* refers to the performance of any significant scientific element or segment of a research project outside of the U.S., either by the recipient or by a research employed by a foreign entity, whether or not grant funds are expended.
8. *Foreign entity* refers to an organization located in a country other than the U.S. and its territories that is subject to the laws of that country, regardless of the citizenship of an Investigator at such organization.
9. *Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.
10. *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.
11. Research is considered to involve *human subjects* when an Investigator conducting research obtains data through intervention or interaction with a living individual, or identifiable private information about a living individual.

12. *Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding (including the APA and its collaborating organizations).
13. *Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on FCOI, 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.
14. *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, which may include, for example, collaborators or consultants.
15. *Manage* means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
16. *Outside Activities and Interests* incorporate an Investigator's non-financial interests and relationships and include the non-compensated provision of services for an outside entity (e.g., consulting, speaking, education, Advisory Board service, and Scientific Advisory Board service), and an Investigator's rights and interests in any patents or copyrights (other than those owned by the APA) when the technology underlying the patent or copyright is related to the Investigator's research at the APA and regardless of whether remuneration was received.
17. *PD/PI* means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.
18. *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).
19. *PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to this policy.
20. *Public Health Service Act* or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*
21. *Research* means 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). 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.



22. *Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this policy.

23. *Significant financial interest* means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - a. 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;
  - b. 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); or
  - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
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 Investigator if the Investigator 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 Investigator, 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 Investigator 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.

24. *Small Business Innovation Research (SBIR) Program* means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.
25. *Small business technology transfer (SBTT)* is a program under the SBIR Program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.
26. *Sponsored/Reimbursed Travel* is any travel expense related to an Investigator's institutional responsibilities that are either paid directly by a third party on behalf of the Investigator so that the exact monetary value may not be readily availability or for which the Investigator is reimbursed by a third party.
27. A *subrecipient* is defined as all non-APA Investigators who are receiving funding awarded to APA, including buy not limited to collaborators, consortium members, consultants, contractors, subcontractors, and subawardees.