



<b>Financial Conflicts of Interest in Public Health Service-Funded Research</b>	
<b>Effective Date: April 17, 2018</b>	<b>Responsible Party: Chief Legal Officer</b>
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## Table of Contents

- I.** Scope and Purpose
- II.** Roles and Responsibilities
- III.** Policy
- IV.** Standards/Procedures
- V.** Related Policies
- VI.** Definitions

### **I. Scope and Purpose**

This policy applies to projects funded by Public Health Service granting agencies, including but not limited to the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

The purpose of this policy is to establish guidelines for recognizing, disclosing, managing, and reporting financial conflicts of interest relating to Public Health Service-funded research. This policy operates in conjunction with other AAMC policies governing conflicts of interest, and is intended to ensure compliance with Federal requirements published in 42 CFR Part 50, subpart F.

### **II. Roles and Responsibilities**

**Responsible** – The Chief Legal Officer is responsible for reviewing and updating this policy, and for securing approval by the Leadership Team.

**Accountable** – Chiefs will be accountable for ensuring this policy is followed within each work unit.

**Consulted** – Finance, Scientific Affairs, and Research and Data Programs are consulted as needed.

**Informed** – All employees.

**All individuals covered by this policy have the responsibility to:**



**Read:** the policy and give careful attention to those subjects that most pertain to your job duties.

**Understand:** the purpose of this policy and your responsibilities for disclosing timely and accurate information, and adhering to any management directives.

**Consult:** your supervisor or Legal Services for additional clarification of this policy.

### III. Policy

This policy sets forth guidelines and procedures for identifying and addressing any potential or actual financial conflict of interest related to research funded by the Public Health Service.

a. Commitment to integrity in PHS-funded research.

The AAMC is committed to ensuring that the financial interests of any individual serving as an Investigator on a PHS/funded AAMC research project (“Covered individuals”) do not conflict or interfere with the integrity of covered research for which the individual has responsibility.

b. Required disclosures.

A covered individual must disclose any significant financial interest (SFI) that relates to or appears to relate to the covered individual’s Institutional Responsibilities, and adhere to any management directive related to managing a financial conflict of interest (FCOI) identified by the AAMC. This disclosure must occur at least annually and within thirty days of acquisition or discovery of a new SFI.

c. Applicability to subrecipients of PHS grant funds.

All subrecipients under a PHS-funded project must have a FCOI policy that meets the requirements published in 42 CFR Part 50, subpart F. The AAMC requires that any subrecipient certify in writing to the AAMC at the time of the award that its FCOI policy complies with FCOI regulations or, alternatively, that it will comply with the AAMC’s policy.

d. AAMC review of significant financial interests and financial conflicts of interest.

Covered AAMC employees must disclose potential or actual FCOIs that could affect the design, conduct, or reporting of PHS-funded research. The Chief Legal Officer (or designee) will review any disclosed SFI to determine its relationship, if any, to the PHS-funded research. The Chief Legal Officer (or designee) will consider the nature of (1) the PHS-funded research, (2) the Investigator’s institutional responsibilities, and (3) the declared



SFIs, to determine if a FCOI exists, and thereafter will take appropriate action to ensure compliance with the requirements of 42 CFR 50.604(f) and any guidelines established by the AAMC.

e. Reporting

Prior to expending any funds through a PHS-funded grant, the AAMC Grants Team will report to the applicable PHS funding agency the existence of any FCOI (including an FCOI attributable to a subrecipient) and the status of any related management plan.

For any FCOI identified by the AAMC subsequent to the initiation of the project, the AAMC Grants Team will report that information to the funding agency, implement a management plan within sixty days of identification, and otherwise comply with 42 CFR 50.605.

For any reported FCOI, the AAMC Grants Team will provide an annual update report to the funding agency for the duration of the project.

If the AAMC identifies an FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the AAMC Grants Team is not required to submit an FCOI report to the funding agency.

#### **IV. Standards/Procedures**

A. Management plans and related actions.

Before performing under a PHS-funded research project, if the AAMC determines that a covered individual's SFI constitutes a FCOI, the AAMC will require the individual to comply with any management plan established for the Investigator until completion of the PHS-funded project, consistent with 42 CFR 50.605(a) and any guidelines established by the AAMC. If warranted, the AAMC will undertake a retrospective review and submit a mitigation report to the PHS funding agency regarding how any identified bias was addressed.

B. Training

For each PHS-funded research project, the Grants Team will inform each Investigator of this policy, the Investigator's disclosure and other compliance responsibilities. The Grants Team will notify the Chief Legal Officer (or designee) whenever the AAMC applies for, or is awarded, a PHS-funded grant or cooperative agreement. Each Investigator must complete training under this policy and covering the relevant Federal regulations as directed by the Chief Legal Officer prior to engaging in research related to any PHS-funded project.



Investigators must complete training every four years and immediately upon any of the following conditions:

- i. The Investigator is new to the AAMC; or
- ii. The AAMC finds the Investigator noncompliant with this policy or a management plan under this policy; or
- iii. There are material changes in requirements under this policy.

C. Record Keeping

Records relating to his policy, including the completion of training, will be maintained by the Grants Team, and will be retained for at least three years after the termination of the activity (date of the final financial report and progress report to the funding agency.)

D. Enforcement

Allegations of violations of this policy shall be carefully examined, and handled through normal management and reporting channels. Violations of this policy will be evaluated as part of the AAMC Performance Management Process and in accordance with the AAMC ***Corrective Action and Performance Improvement Policy***.

E. Website posting of Policy

The AAMC will publish this policy on its publicly available website and will include a contact person for any requests for information.

F. Public requests for FCOI information.

The AAMC will list a contact person on its publicly available website and provide a written response to any requestor within five business days of a request for information concerning any existing SFI related to PHS-funded research that constitutes an FCOI. The response will include information required by 45 CFR 94.5(a)(5)(ii).

## V. Related Policies

AAMC Conflict of Interest Policy

AAMC Corrective Action and Performance Improvement Policy

## VI. Definitions

A. **Financial Conflict of Interest** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.



**B. Immediate family** means an Investigator's spouse, domestic partner, and anyone who receives directly or indirectly, more than one half of his or her support from the Investigator or from whom the Investigator receives, directly or indirectly, more than one half of his or her support.

**C. Investigator** means the project director or any other person regardless of title who is responsible for the design, conduct, or reporting of research funded by the PHS, which may include collaborators, subcontractors, and consultants.

**D. Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the AAMC.

**E. Significant Financial Interest** means one or more of the following interests of the Investigator and those of his/her immediate family:

- i. A significant financial interest exists if the value of any remuneration received from any publicly traded entity in the 12 months preceding the disclosure and the value of any equity interest in the entity totals to exceed \$5000. Remuneration includes salary and any payment for services not otherwise identified as salary as well as equity interest including stock, stock option or ownership interest. In regard to non-publicly traded entities, a significant financial interest exists if the value of remuneration exceeds \$5000 or when the Investigator and his/her family hold *any* equity interest or *any* intellectual property rights and interests. Note that there is no minimum value for equity interest in non-publicly traded entities.
- ii. A significant financial interest includes any reimbursed or sponsored Investigator travel related to his or her institutional responsibilities. Reimbursed or sponsored travel includes travel which is paid on behalf of the Investigator but not reimbursed directly to the Investigator. Note exclusions below relating to source of reimbursed or sponsored travel.

The following are excluded from the definition of significant financial interest:

- a. salary, royalties or other remuneration paid by the AAMC to the Investigator;
- b. intellectual property rights assigned to the AAMC and agreements to share royalties related to those rights;
- c. 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;



- d. income from seminars, lectures or teaching engagements sponsored by a federal, state, or local agency or institution of higher education or academic hospital, medical center or research institute affiliated with an institution of higher education;
- e. income from service to advisory committees or review panels associated with the same organizations identified in item d immediately above;
- f. travel reimbursed by an organization identified in item d immediately above.

**VII. Revision History**

Version	Date	Revision Description	Author
1.1	4/17/18	LT Re-Approval of Policy (Formatting changes only)	Frank Trinity

**VIII. Exhibits**

None.