



## **AMGA Financial Conflict of Interest Policy (FCOI) for Research Funding Under the Public Health Service Act and National Institutes of Health**

The Code of Federal Regulations ([42 CFR Part 50, Subpart F](#)) states all organizations and individuals participating in, conducting, or planning to participate in research funded under the Public Health Service Act, including the National Institutes of Health, must establish policies to ensure research is free of bias from Investigators' **Financial Conflicts of Interest** (FCOI).

### **General Purpose**

The purpose of these policies and procedures is to assist AMGA investigators and other members of research study teams with disclosure of **significant financial interests (SFIs)**. These policies explain AMGA's process for management of potential or perceived FCOIs relating to research conducted by AMGA or by investigators/institutions acting as Subrecipients (see section on "Subrecipients") that is funded by the Public Health Service Act including the National Institutes of Health (PHS/NIH) agency. FCOI disclosure requirements generally apply to Institutions and Principal Investigators, but they can also apply to other members of the study team whenever the financial interest in question may affect the design, conduct, or reporting of research. The objectives of these FCOI policies and procedures are to:

1. Ensure the design, conduct, and reporting of AMGA research supported by PHS/NIH funding is free of bias
2. Protect the integrity of AMGA's publicly funded research activities
3. Maintain high ethical standards for the conduct of AMGA research
4. Adhere to all applicable federal FCOI regulations
5. Protect the reputation and research credibility of AMGA, our member organizations, and other partners participating in research.

These principles and procedures include:

1. Identification of FCOIs that could, actually or potentially, influence or introduce bias into research activities engaged in by AMGA or on behalf of AMGA by member organizations or other Subrecipients;
2. Establishment of a process for review of potential, significant FCOIs; and
3. Development of procedures for the management of FCOIs if and when they may arise.

### **Scope**

This FCOI Policy applies to research officials and personnel as defined herein, it relates to review and management of FCOI related to PHS/NIH-funded AMGA research. This policy does not replace or

supersede other AMGA conflict of interest policy(ies) that are not related to AMGA's PHS/NIH-funded research.

## Definitions

**Disclosure:** Refers to the investigator's reporting of significant financial interest to AMGA and when appropriate to the applicable PHS/NIH funding agency.

**Financial Interest:** Any item of monetary value, whether or not the value is readily ascertainable.

**Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct and reporting of research. (See Figure 1 below.)

**Institution:** Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that applies for or receives research funding from a PHS/NIH agency by means of a grant or cooperative agreement.

**Investigator:** Principal Investigator (PI) or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a PHS/NIH agency who proposes such funding (the term "investigator" may also include, for example, key personnel and Investigators of Subrecipient institutions).

**Management Plan:** A document that outlines and implements measures to actively reduce, mitigate, or eliminate an actual or potential FCOI held by an Investigator to ensure the design, conduct, and reporting of research is free from bias.

**Regulation or FCOI Regulation:** Refers to [42 CFR Part 50, Subpart F](#), Promoting Objectivity in Research is the U.S. Federal Code, which applies to grants and cooperative agreements funded by PHS/NIH agencies. PHS federal agencies include the Agency for Health Care Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

**Research:** The regulation includes basic and applied research funded by PHS/NIH agencies or other statutory authority, such as a research grant, career development award, NIH center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Senior/Key Personnel:** Includes the Project Director/Principal Investigator (PD/PI) and any other persons identified as senior/key AMGA research personnel (or those of a Subrecipient) included on the grant application, proposal, progress report, or any other report submitted to the PHS/NIH funding agency by AMGA under the [FCOI Regulation](#).

## Significant Financial Interest (SFI)

- 1) A financial interest consisting of one or more of the following interests of the Investigator (and/or the investigator's spouse and/or dependent children) that reasonably appears to relate to the investigator's research and/or institutional responsibilities.
  - i) 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 (12) 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. 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;
  - (ii) 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 (12) 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);
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income related to such rights and interests; or
  - (iv) Travel reimbursed or sponsored by a third party (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse and dependent children) related to the Investigator's Institutional Responsibilities. This disclosure requirement excludes travel paid for by AMGA or travel that is reimbursed or sponsored by a U.S. 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
  - (v) Holding any position of influence (e.g., director, officer, trustee, dean, or faculty) in a non-AMGA related entity.
- 2) The term significant financial interest does not include the following types of financial interests:
  - i) Salary, royalties, or other remuneration paid by AMGA to the Investigator if the Investigator is currently employed or otherwise appointed by AMGA, including intellectual property rights assigned to AMGA and agreements to share in royalties related to such rights;
  - ii) Income from investment vehicles, such as mutual funds and retirement accounts when the Investigator does not directly control the investment decisions;

- iii) Income from seminars, lectures, or teaching engagements sponsored by a U.S. 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
- iv) Income from service on advisory committees or review panels for a U.S. 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.

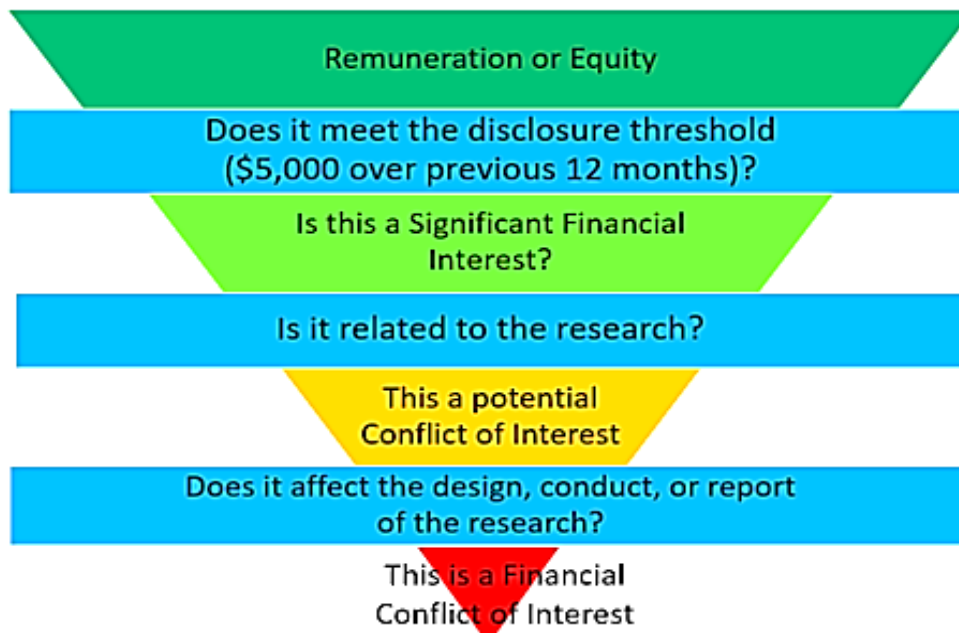
### What is a Financial Conflict of Interest?

A Financial Conflict of Interest (FCOI) arises when an investigator’s financial interests (or those of his spouse or dependent children) compromise or have the potential to compromise the investigator’s judgment in performing his or her research duties. These conflicts can arise when an existing or potential financial or other potential monetary interest may:

- a) Impair or reasonably appears to impair the investigator’s independence of judgment in the discharge of his/her research responsibilities; or
- b) Result in personal gain or advancement at the expense of the research/research subjects.

***Financial conflicts of interest must be: (1) disclosed, (2) eliminated, or (3) properly managed.***

**Figure 1. What is a Financial Conflict of Interest?**



## Investigator Responsibilities

AMGA Investigators must comply with AMGA’s FCOI policies and procedures consistent with the [FCOI regulation](#) on research that is PHS/NIH funded. FCOI requirements for individual Investigators include completion of FCOI training and disclosure of information about *relevant SFIs* for Investigators engaged in, or planning to engage in, research supported by a PHS/NIH funding agency. (See section on disclosure below and AMGA’s [Investigator Disclosure Form](#) for more information). In the case of Investigators acting as a Subrecipient on PHS/NIH-funded AMGA grant, Investigators must provide written confirmation of their compliance with FCOI regulation through policy(ies) established by their institutions. If the Subrecipient cannot provide confirmation of FCOI compliance, they will be subject to compliance under AMGA FCOI policies and procedures (see section on “Subrecipients” for more information).

### Training

**FCOI Training Requirements for AMGA Investigators:** All AMGA Investigators are required to complete FCOI training before engaging in research funded by a PHS/NIH agency. Investigators with incomplete or out-of-date FCOI training (more than 4 years) must complete the [NIH FCOI Training Tutorial](#). Investigators are responsible for updating NIH FCOI training at least once every 4 years. Newly hired investigators must also complete the [NIH FCOI Training Tutorial](#) immediately if working on a PHS/NIH-funded grant/agreement. All AMGA Investigators must renew their FCOI training whenever AMGA policies or the [FCOI regulation](#) are updated.

**Training for Investigators under FCOI Management:** Investigators who are found not to be in compliance with [FCOI Regulation](#) or who are under FCOI Management Plans (see definition of “management plans” for more information) must immediately retake and complete the [NIH FCOI Training Tutorial](#).

**Training for Investigators of Subrecipient Organizations:** Investigators at institutions AMGA has included as a Subrecipient on a PHS/NIH-funded grant or agreement (see section on “Subrecipient” for more information) either must complete the [NIH FCOI Training Tutorial](#) and provide evidence of completion or provide certification of their satisfactory completion of equivalent, up-to-date FCOI training (satisfactorily completed within the past 4 years).

All Investigators who take FCOI training must provide a Certificate of Completion that includes their full name and the date of their satisfactory completion and send it to:

[research@amga.org](mailto:research@amga.org).

*Investigators who cannot provide a current FCOI training certificate will not be able to participate in PHS/NIH-funded AMGA research.*

## Disclosure

**Annual Disclosure Requirements:** AMGA Investigators must report all SFIs *that reasonably relate or appear to be related* to the Investigator’s discharge of AMGA research responsibilities on an annual basis. AMGA Investigators must use [AMGA’s Investigator Disclosure Form](#) to report SFIs. SFIs include remuneration, equity interest, intellectual property rights, and interest including sponsored travel received within the preceding twelve (12) months that, when aggregated, exceed \$5,000. (See definition of “Significant Financial Interest” for more information.)

**Ad Hoc and Ongoing Disclosure Requirements:** New Investigators to AMGA must complete and submit an [AMGA Investigator Disclosure Form](#) within thirty (30) days of employment or appointment to a research grant funded by a PHS/NIH agency. All Investigators have an ongoing obligation to update SFI disclosure forms when changes occur that could potentially affect their research duties. Newly acquired SFIs should be reported to AMGA within thirty (30) days of their discovery (e.g., through purchase, marriage, or inheritance). Ongoing disclosure obligations include reimbursed or sponsored travel expenses exceeding the \$5,000 threshold (see definition for “significant financial interest” for more information). Travel expenses paid by a third party through a grant or a contract with AMGA do not need to be reported.

**Disclosure Related to SFI of Investigators of Subrecipients:** Reporting responsibilities related to SFI of Investigators/Institutions acting as Subrecipients in PHS/NIH-funded AMGA research are addressed in a later section entitled “Subrecipients.”

***Each Investigator is responsible for ensuring that he/she makes the necessary SFI disclosures to AMGA required by this policy.***

***Investigators should complete and send their AMGA Investigator Disclosure Forms to [research@amga.org](mailto:research@amga.org)***

***Downloadable copies of AMGA’s FCOI Policies and Procedures, Investigator Disclosure Form, and other resources to help Investigators understand FCOI regulations are available at: [amga.org/performance-improvement/best-practices/research-analytics/research\\_policies\\_procedures](http://amga.org/performance-improvement/best-practices/research-analytics/research_policies_procedures).***

***For questions about AMGA’s FCOI policies and procedures, contact: [research@amga.org](mailto:research@amga.org)***

**Reporting Suspected FCOIs:** Any individual involved in research at AMGA may report suspected FCOIs or alleged violations of FCOI Policy to [research@amga.org](mailto:research@amga.org).

## AMGA Institution Responsibilities

**Review, Reporting, and Management Procedures:** AMGA's Office of the Vice President of Research and Analytics (the "Research Office") is responsible for providing Investigators with information to enable proper reporting of SFIs. The Research Office also monitors compliance with training and reporting requirements under the [FCOI regulation](#) and keeps FCOI policies and procedures up-to-date. Other responsibilities include:

- Initiating and managing training and disclosure policies and procedures for Investigators in accordance FCOI regulation;
- Maintaining an up-to-date version of FCOI policies and procedures on AMGA's website;
- Conducting preliminary reviews of all SFI disclosures related to PHS/NIH-funded AMGA research;
- Forwarding SFI disclosure forms, review summaries, and other pertinent information to AMGA's Research Steering Committee (see below) for cases where an SFI is in question.
- Making recommendations to the AMGA Research Steering Committee on a course of action for further inquiry and/or suggested strategies to manage potential or identified FCOIs.
- In cooperation with the AMGA Research Steering Committee, overseeing initial and ongoing reporting of FCOIs and other pertinent information to PHS/NIH funding agencies;
- Assisting the AMGA Research Steering Committee in their oversight of Investigator compliance with FCOI Management Plans;
- Assisting the AMGA Research Steering Committee in oversight regarding retrospective review of, and procedures for, managing FCOIs that are not reported, identified, or managed in a timely manner; and
- Maintaining records relating to training, SFI disclosures, SFI and FCOI reviews, and management plans.

### Review of Financial Conflicts of Interest

**AMGA Research Steering Committee:** AMGA's Chief Executive Officer (CEO) appoints members to AMGA's Research Steering Committee and serves as its Chair. Other officers include the Vice President of Research and Analytics, Chief Medical Officer, Chief Medical Informatics Officer, and the AMGA Compliance Officer. The Committee reviews all prospective AMGA research activities.

The AMGA Research Steering Committee has oversight of inquiries into potential FCOIs and will make any final determinations about SFIs with regard to whether they compromise the design, conduct, or reporting of AMGA Research. The Research Steering Committee may consult with AMGA Legal Counsel as needed to ensure maximum confidentiality and privilege for any ensuing FCOI inquiry. With support from the Research Office, the AMGA Research Steering Committee is responsible for the following activities:

- Implement of procedures to ensure compliance with all reporting and other FCOI requirements included in the final AMGA and PHS/NIH funding agreement;
- Formal review and approval of operating procedures related to the management of potential or identified FCOIs;
- Review and investigation of allegations of noncompliance with FCOI Regulation, AMGA's FCOI policies and procedures, or with a FCOI Management Plan;
- Oversight of official inquiries, investigations and all formal review of allegations, reports, and recommendations regarding SFIs when in question regarding a potential FCOI;
- Request and review of additional materials as needed from Investigators and other sources to fully evaluate the SFI and its potential to bias AMGA research;
- In investigating any violation, determine if the violation has biased the design, conduct, or reporting of the research;
- Determine when an SFI/FCOI requires an FCOI Management Plan;
- Oversee the development of and approve all FCOI Management plans and implement measures to reduce, mitigate, or eliminate an actual/potential FCOI;
- With respect to research involving human subjects, after evaluation of the SFI, recommend appropriate management measures and reports to IRBs;
- Determine what corrective actions, disciplinary sanctions, and reporting are appropriate to mitigate the FCOI;
- In cases where a FCOI Management Plan exists, implement and oversee ongoing compliance with the FCOI Management plan; and
- Decide when it is appropriate to report an SFI/FCOI to the applicable PHS/NIH funding agency.



*Per [FCOI regulation](#), Investigators cannot make the decision about whether an SFI must be managed or whether it is a FCOI that should be eliminated.*

## **FCOI Management Plans**

In cases of an FCOI, the AMGA Research Steering Committee, with support from the Research Office, will develop plans for the management, reduction, or elimination of identified SFIs that could potentially result in an FCOI. Each FCOI Management Plan will take steps to ensure the objectivity of the research and may include, but are not limited to:

- Implementing corrective actions, which can include suspension of the research project if deemed necessary to maintain the objectivity of the research;
- Promptly notifying the PHS/NIH funding agency of any project for which research has been suspended pending conclusion of a retrospective review (described below);
- Reporting results of FCOI investigations to the PHS/NIH funding agency along with any appropriate corrective actions to maintain the objectivity of the Research;
- Disclosure of the Investigator's Significant Financial Interest to the public;
- Disclosure of the Investigator's Financial Interests to participants if research involves human subjects;
- Appointment of an independent reviewer for data, manuscripts, and/or presentations;
- Modification of the research proposal or plan;
- Changes in the personnel or duties of personnel related to the research (e.g., removal of an Investigator from all or a portion of the research);
- In consultation with the Chief Operations Officer or his/her designee, decide on appropriate sanctions or disciplinary actions in accordance with AMGA's Employee Handbook and other established AMGA policies and procedures (Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination. AMGA will promptly notify the affected Investigator in writing of the results of the investigation and plans for disciplinary action, if applicable.);
- Manage FCOIs of Investigators/Institutions acting as Subrecipients (may include severance of the relationship(s) that created the financial conflict).; and
- Other means to reduce or eliminate the questionable SFI.

**For any *FCOI Management Plan*, the affected Investigator must agree in writing to follow all prescribed actions and procedures to manage, reduce, or eliminate an identified FCOI *before* the research can proceed.**

## **Retrospective Review Procedures**

In addition to the above review and sanctions, when an FCOI is not identified or managed appropriately at the outset of the research, AMGA shall conduct a retrospective review of the research at issue. This includes any failure by an Investigator to disclose a SFI that is determined by AMGA to be an FCOI, failure to review or manage an FCOI, or failure by the Investigator to comply with the FCOI Management Plan. AMGA's Research Committee is responsible for overseeing the following retrospective review procedures:

1. AMGA will implement, on at least an interim basis, a FCOI Management Plan that specifies the actions that have been and will be taken to manage the FCOI going forward.
2. Within 120 days of AMGA's determination of noncompliance, AMGA will complete a retrospective review of the Investigator's activities and the affected research project to determine whether any research, or portion thereof, conducted during the period of noncompliance, was biased in design, conduct, or reporting.
3. AMGA will document the retrospective review and include the following information:
  - a) Project number;
  - b) Project title;
  - c) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - d) Name of the Investigator with the FCOI;
  - e) Name of the entity with which the Investigator has a FCOI;
  - f) Reason(s) for the retrospective review;
  - g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - h) Findings of the review; and
  - i) Conclusions of the review.
4. For PHS/NIH-sponsored research, if the results of the retrospective review indicate bias, AMGA is required to notify the PHS/NIH funding agency promptly and submit a mitigation report. The mitigation report must include, at a minimum:
  - a) The key elements documented in the retrospective review;
  - b) A description of the impact of the bias on the research project; and

- c) AMGA's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Thereafter, AMGA will submit to the PHS/NIH awarding agency FCOI Reports annually. Depending on the nature of the FCOI, AMGA may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS/NIH-funded research.

7. For any clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Investigator with an unreported/unmanaged FCOI, AMGA will 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.

### **Reporting FCOI to PHS/NIH Funding Agencies**

The FCOI regulation requires AMGA to report substantial FCOI to the applicable PHS/NIH -funding agency. No expenditure of funds can occur on PHS/NIH-supported research in cases where an FCOI Management Plan is required until after the PHS/NIH funding agency has received an FCOI Report that must include:

- 1) Project number;
- 2) PD/PI or contact PD/PI if multiple PD/PIs exist;
- 3) Name of the Investigator with the FCOI;
- 4) Name of the entity with which the Investigator has a FCOI;
- 5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 6) Value of the financial interest, or a statement of why the SFI value cannot be readily determined;
- 7) A description of how the financial interest relates to the PHS/NIH-funded research and why the SFI could potentially compromise the research; and
- 8) A description of key elements of AMGA's FCOI Management Plan:
  - a. Role and principal duties of the conflicted Investigator in the research;
  - b. Conditions of the FCOI Management Plan;
  - c. How the FCOI Management Plan safeguards future objectivity of the research;
  - d. Confirmation of the Investigator's agreement to comply with to the FCOI Management Plan;
  - e. How the FCOI Management Plan will be monitored to ensure Investigator compliance; and
  - f. Other information as needed or requested by the PHS/NIH funding agency.

**AMGA will provide a FCOI Report with the information above to the appropriate PHS/NIH funding agency within sixty (60) days of identification of the FCOI.** Each award year, AMGA will provide the PHS/NIH funding agency with an annual FCOI Report updating the status of the FCOI and include any changes that have been made to the FCOI Management Plan. This will continue for the duration of the project (includes extensions with/without funding). The annual AMGA FCOI Report will specify whether the FCOI continues to be managed or explain why the FCOI no longer exists. **AMGA must report to the PHS/NIH-funding agency on the FCOI at the time of the progress report.**

## **Reports to the Public for FCOI on PHS/NIH-Supported Research**

[FCOI regulation](#) requires AMGA provide, in writing, information requested on any FCOI occurring after August 24, 2012. Requests for information must be in writing and received through U.S. mail. The request must identify the specific PHS/NIH project number and the name of Investigator for whom information is sought. The request must also include the recipient's name and a physical street address for the response (a post office box is not accepted). AMGA will note in its written response whether the information is current and whether it is still subject to annual FCOI status reports.

The following information will be provided to the requestor:

- 1) Project number;
- 2) Name of the Investigator with an FCOI;
- 3) Investigator's title and role with respect to the research project;
- 4) Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium); and
- 5) Value of the Financial Interest (in ranges), or a statement that the interest is one whose value cannot be readily determined.

## **Subrecipients**

**Monitoring:** For AMGA research that is PHS/NIH-funded involving subcontractors, subgrantees or sub-awardees at other institutions (collectively "Subrecipients"), AMGA will be responsible for ensuring the Subrecipient institution and its Investigators comply with FCOI regulation. AMGA will take all reasonable steps to ensure any Investigator/institution acting as a Subrecipient complies with Federal FCOI regulations by:

(1) Requiring a written agreement from Subrecipient that establishes whether AMGA's policy or the Subrecipient's policy will apply to the Subrecipient Investigators.

- a. If the Subrecipient policy is used, the Subrecipient must certify that their FCOI policy is compliant with current [FCOI Regulation](#). **Subrecipients must report to AMGA as the awardee institution any identified FCOI no later than 45 days after identification of the FCOI** by the

Subrecipient. AMGA will report the details of the FCOI to the funding agency as required under applicable regulations/policies.

b. If AMGA’s policy is used, the Subrecipient must ensure that its Investigators submit the SFI Disclosure Form to AMGA prior to the time of application or in the case of an ongoing award, at the time the Subrecipient signs an institutional letter of support.

2) Reporting to the PHS/NIH funding agency any Subrecipient FCOIs prior to the execution of the sub-agreement or within sixty (60) days of identification of a new FCOI by the Subrecipient or AMGA during the term of the sub-agreement.

***This policy shall be reviewed by the Office of the Vice President of Research and Analytics and the AMGA Research Steering Committee at least every 10 years from the effective date below, or when federal FCOI regulation changes, whichever comes first.***

**Effective Date:** September 12, 2022  
**Last Updated:** September 12, 2022  
**FCOI Contact:** Cindy Shekailo, Compliance Officer  
 E-mail: cshkailo@amga.org  
 Phone: 703.838.0033 ext. 361

Summary FCOI Reporting Timelines and Compliance Procedures		
<b>Annually</b>	<b>AMGA must submit Investigator Disclosure of SFI</b>	AMGA Investigators must report all SFIs <i>that reasonably relate or appear to be related</i> to the Investigator’s discharge of AMGA research responsibilities on an annual basis. AMGA Investigators must use
	<b>AMGA must submit an FCOI Status Report (Each award year as part of the progress report.)</b>	AMGA will report to the PHS/NIH funding agency on an FCOI at the time of the progress report. The annual FCOI Report will specify whether the FCOI continues to be managed or explain why the FCOI no longer exists.
<b>Within 30 days of hire or before assignment to a PHS/NIH project</b>	<b>Investigators must complete an AMGA FCOI Disclosure Form</b>	<a href="#">AMGA Investigator Disclosure Form</a> within thirty (30) days of employment or appointment to a research grant funded by a PHS/NIH agency.
<b>Prior to sub-agreement execution</b>	<b>AMGA will submit to PHS/NIH funding agency the</b>	AMGA must report to the PHS/NIH funding agency any Subrecipient FCOIs prior to the execution of the sub-agreement.

	<b>Subrecipients SFI Disclosure Report.</b>	
<b>Within 45 days of discovery</b>	<b>Subrecipients must report any previously unidentified potential FCOIs to AMGA.</b>	Subrecipients must report to AMGA (as the awardee institution) any previously unidentified SFI that potentially could be an FCOI for review and determination no later than 45 days after discovery/identification.
<b>Within 60 days of new discovery for ongoing awards</b>	<b>AMGA will submit to PHS/NIH funding agency new/newly discovered Subrecipient FCOI</b>	AMGA must report to the PHS/NIH funding agency any Subrecipient FCOIs within sixty (60) days of identification for a new FCOI by the Subrecipient in an ongoing award.
<b>Within 60 days of discovery</b>	<b>AMGA must report FCOI's not previously identified or disclosed to PHS/NIH funding agency.</b>	Whenever AMGA and/or a subrecipient identifies an SFI not originally disclosed, identified, reviewed, or managed in a timely manner, AMGA will have 60 days to review and determine whether an FCOI exists and make a report when an FCOI is found to the PHS/NIH funding agency.
<b>Within 120 days of non-compliance</b>	<b>AMGA must complete a Retrospective Review of Investigator's Activities.</b>	Upon a determination of noncompliance with <a href="#">FCOI regulation</a> (in the case of previously undisclosed FCOI), AMGA will complete a retrospective review of the Investigator's activities and the affected research project to determine whether the research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting.
<b>Immediately</b>	<b>AMGA must notify PHS/NIH funding agency if bias is found during retrospective review</b>	If bias is found, AMGA will notify PHS/NIH agency promptly (contact the Contracting Officer). Submit mitigation report.