



ASAM American Society of
Addiction Medicine

Policies & Procedures
ASAM Financial Conflict of Interest (FCOI)
Investigators

Created May 2021

American Society of Addiction Medicine

Financial Conflict of Interest Policy / Investigators

A. Introduction

To further the purposes for which the American Society of Addiction Medicine (ASAM) is organized and to maintain the excellent reputation in which it is held by the public and the medical profession, it is important that ASAM's grant funded activities not be influenced unduly by any special interests of individual members. ASAM depends upon its staff and members to shape funding requests and manage funded projects including reporting. The actions of the ASAM staff and members acting in the role of Investigator must not be inappropriately affected by outside financial influences. Therefore, it has always been and continues to be important to identify actual or potential financial conflicts of interest which might improperly affect ASAM funding requests and grant funded activities or cooperative agreements.

ASAM's Financial Conflict of Interest (FCOI) policy for Investigators aligns with the Public Health Service (PHS) of the U.S. Department of Health and Human Services (HHS) requisite of research funding recipients to comply with the National Institute of Health (NIH) Grants Policy Statement FCOI policy requirements. To meet this need, this policy details a formal system for the disclosure and evaluation of possible financial conflicts of interest.

B. Purpose

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest, to safeguard the integrity of the American Society of Addiction Medicine (ASAM) and comply with the federal regulations (42 CFR Part 50 Subpart F).

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." (FCOI Regulation) as implemented in the 2011 Final Rule for grants and cooperative agreements. *See NIH Grants Policy Statement [4.1.10 Financial Conflict of Interest \(nih.gov\)](#)*

In accordance with the required regulations of NIH funding applicants and/or award recipients, ASAM will maintain an up-to-date, written and enforced policy for Investigators. ASAM will certify, in each application for funding, that it will identify and manage FCOI and provide initial and ongoing FCOI reports. ASAM will certify that it will make FCOI and Significant Financial Interest (SFI) information available to HHS, promptly, upon request and

fully complies with the regulations' requirements.

The PHS of the U.S. Department of HHS requires principal Investigators and co-principal Investigators to certify that they have read and understood the institution's conflict of interest policy, have made all required financial disclosures, and will comply with any conditions or restrictions imposed by the institution to manage, reduce, or eliminate actual or potential conflicts of interest. Conflicts of interest, if any, must be, or prior to the expenditure of funds under an award will be satisfactorily managed, reduced or eliminated in accordance with the institution's conflict of interest policy, and/or disclosed to PHS.

C. Definitions

Disclosure of significant financial interests

Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI)

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. A conflict of interest is defined as a situation in which an Investigator acting on behalf of ASAM (officer, volunteer and staff) is in a position to derive personal financial benefit as an Investigator. Financial interest held by an ASAM Investigator could influence or be perceived as influencing the Investigator to act for their own personal benefit or for the benefit of an immediate family member or business associate. The financial interest does not need to be contrary to the financial interests of ASAM to be considered a conflict.

FCOI report

ASAM's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest

Anything of monetary value, whether the value is readily ascertainable.

HHS

The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institutional responsibilities

An Investigator's professional responsibilities on behalf of ASAM, and as defined by ASAM in its policy on financial conflicts of interest, 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 Monitoring Boards.

Investigator

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.

Manage

Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI

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 subpart.

PHS

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).

PHS Awarding Component

The organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act

The statute codified at 42 U.S.C. 201 et seq.

Research

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 subpart, 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.

Senior/key personnel

The PD/PI and any other person identified as senior/key personnel by ASAM in the grant application, progress report, or any other report submitted to the PHS by ASAM under this subpart.

Immediate Family Member

An immediate family member is defined as a member's spouse, significant other, children, and parents and/or any individual residing in the household.

Note: throughout the document when ASAM Investigator is referenced, the reference includes all immediate family members for which that person will need to disclose FCOI

Significant Financial Interest (SFI)

1. A financial interest consisting of one or more of the following interests of the Investigator and Investigator's immediate family members 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.
 3. The term significant financial interest does not include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by the ASAM to the Investigator if the Investigator is currently employed or otherwise appointed by ASAM, including intellectual property rights assigned to ASAM and agreements to share in royalties related to such rights;
 - b. 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;
 - c. 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
 - d. 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.

D. Investigator Disclosure Process

ASAM requires each Investigator or key personnel who is planning to participate in the PHS/NIH-funded research, or in the federal grant submission pre and/or post award, to disclose SFI, related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI as defined above. SFI are disclosed on the ASAM Significant Financial Interest Disclosure Form (SFIDF). The Investigator(s) will submit the SFIDF to the

Grant Program Manager who will submit the SFIDF(s) to ASAM's designated official, the Chief Operating Officer (COO) no later than the time of application for PHS-funded research.

Disclosures of reimbursed or sponsored travel must include: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. If ASAM determines a potential FCOI, additional information such as monetary value will be requested.

ASAM requires each Investigator who is participating in the PHS/NIH-funded research to submit an updated disclosure of SFI annually, in accordance with the specific budget period start date(s) during the project period of the award. Such disclosure(s) will include any information that was not disclosed previously to ASAM. (e.g., any FCOI identified on a PHS-funded project that was transferred from another Institution) and will include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

ASAM requires each Investigator who is participating in the PHS/NIH-funded research to submit an updated disclosure of SFI within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

An Investigator is under a continuing obligation to disclose any SFI or the appearance of financial conflict, as soon as it is known, or reasonably should have been known.

Annual updates and newly acquired SFI are reported using the SFIDF.

It will be the responsibility of the PI of a research funded project to identify all Investigators who are required to disclose SFI under this policy and to ensure that a SFIDF is prepared and submitted. In addition, the PI will be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. To assist PIs with this responsibility, the Grant Program Manager will send out reporting reminders, SFIDF forms, and receive completed forms for review, this will occur annually and prior to application submissions. PIs are responsible for SFIs submissions that occur between these reporting timelines.

Advance approval by the CEO is required prior to engaging in government-sponsored research. A SFI review must be completed of all Investigators before any expenses are incurred under an award. ASAM's CEO/Executive Vice President provides approval as signatory of the research agreement, simple agreement, or contract.

E. Investigator FCOI Training

In accordance with the FCOI regulation, ASAM requires each Investigator and subrecipient Investigator to complete training prior to engaging in PHS/NIH-funded research or immediately upon approval of the initial funding award. All Investigators are required to complete the training at least every four (4) years and immediately under the following circumstances:

1. ASAM FCOI policy changes that affects the Investigator requirements
2. An Investigator is new to ASAM
3. ASAM finds that an Investigator is not in compliance with the ASAM's FCOI policy management plan.

The NIH FCOI tutorial was designed to provide education training on what constitutes a FCOI. The course is accessible on NIH's Office of Extramural Research Financial Conflict of Interest web page found at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

ASAM requires Investigators to obtain a certificate of completion of the NIH FCOI tutorial to satisfy the training requirement. The certificate must be submitted to ASAM's Grant Program Manager upon completion. The Grant Program Manager will submit all training certificates to the COO.

F. Designated Official SFI Review and FCOI Determination

ASAM's COO will review SFI disclosures related to the Principle Investigator's (PI) institution responsibilities to determine an actual or potential FCOI. The PI will review SFI disclosures related to the Investigator(s) institutional responsibilities and will alert the COO of an actual or potential FCOI. A FCOI exists, when ASAM, through the COO, reasonably determines that the Investigator has a SFI related to the research project that:

1. Could directly and significantly affect the design, conduct or reporting of NIH funded research
2. Is in an entity whose financial interest could be affected by the research.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research. When there is reason to believe that an actual or potential FCOI exists, or the appearance of an FCOI exists, between the interests of ASAM and that of an Investigator, the ASAM Ethics Committee will ultimately be responsible for determining the appropriate response.

The COO will notify ASAM's Ethics Committee and take appropriate action to protect the interests of ASAM, its employees, its clients, and its research participants. The Ethics Committee will report their determinations and suggestions for management of the conflict to the ASAM Executive Committee and/or Board of Directors who will render a decision on the final action.

G. Management of FCOI

ASAM will make every effort to ensure that FCOIs do not bias research conducted by Investigators and that do not place clients, research participants, or others at risk.

Prior to ASAM's expenditure of any funds under a PHS/NIH-funded research project, the COO will review all Investigator disclosures of significant financial interests; determine

whether any significant financial interests relate to PHS/NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that will specify the actions that have been, and will be, taken to manage such financial conflict of interest.

Prior to ASAM's expenditure of any funds under a PHS/NIH-funded research project, ASAM will provide to NIH a FCOI report regarding any Investigator SFI found by ASAM to be an FCOI, in accordance with the regulation.

If the COO, through the recommendation of the ASAM Ethics Committee and approval of the ASAM Executive Council and/or Board of Directors, determines that an FCOI exists or has the potential to exist, they will determine what conditions or restrictions, if any, should be imposed by ASAM to manage these actual or potential conflicts.

Examples of conditions or restrictions that might be imposed by ASAM to manage FCOIs include, but are not limited to:

1. Public disclosure of SFIs; (e.g., when presenting or publishing the research; to staff members working on the project; to ASAM's review board(s) or committees.
2. Monitoring and management of the FCOI by ASAM's COO;
3. Review of the research protocol by independent reviewers;
4. Monitoring of the research by independent reviewers;
5. Modifications of the research plan;
6. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
7. Disqualification of the Investigator from participation in all or a portion of the research funded by PHS or NIH;
8. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
9. Severance of relationships that create actual or potential conflicts of interest.

If ASAM does impose conditions or restrictions upon an Investigator with respect to managing a FCOI, a management plan will be prepared that details the conditions or restrictions imposed on the Investigator in the conduct of the project or regarding their relationship with ASAM. The management plan will be signed by the Investigator and ASAM's EVP. Actual or potential FCOI will be satisfactorily managed, reduced, or eliminated, and or they will be disclosed to the funding agency for action.

The key elements of ASAM's FCOI management plan include:

1. Role and principal duties of the conflicted Investigator in the research project
2. Conditions of the management plan
3. How the management plan is designed to safeguard objectivity in the research project
4. Confirmation of the Investigator's agreement to the management plan
5. How the management plan will be monitored to ensure Investigator compliance
6. Other information as needed

ASAM requires when an Investigator is new to participating in a research project or when an existing Investigator discloses a new SFI, ASAM's COO will review the disclosures within sixty (60) days and determine whether the SFI is related to PHS/NIH-funded research and whether a FCOI exist; and if so implement, at least on an interim basis, a management plan specifying the actions that have and will be taken to manage the FCOI.

If ASAM identifies a SFI that was not disclosed in a timely manner, including failure by the Investigator to disclose, or was not previously reviewed by ASAM during an ongoing PHS/NIH funded project, ASAM's COO will review the disclosures within sixty (60) days and determine whether the SFI is related to PHS/NIH-funded research and whether a FCOI exist; and if so implement, at least on an interim basis, a management plan specifying the actions that have and will be taken to manage the FCOI.

In addition, whenever a FCOI is not identified or managed in a timely manner, including Investigator's failure to disclose or ASAM's failure to review and manage a FCOI, or failure with the Investigator to comply with the FCOI management plan, ASAM will within one hundred and twenty (120) days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any PHS/NIH-funded research, portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of the research.

ASAM will document the retrospective review including but not limited to the following:

1. Project number
2. Project title
3. PD/PI or contact PD/PI if a multiple PD/PI model is used
4. Name of the Investigator with the FCOI
5. Name of the entity with which the Investigator has a financial conflict of interest
6. Reason(s) for the retrospective review
7. Detailed methodology used for the retrospective review
8. Findings of the review
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, ASAM will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, ASAM is required to notify NIH promptly and submit a mitigation report to NIH.

The mitigation report must include, at a minimum,

1. The key elements documented in the retrospective review
2. Description of the impact of the bias on the research project
3. ASAM'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).

ASAM will submit FCOI reports annually to NIH. Depending on the nature of the FCOI, ASAM may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS/NIH-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

If the PHS/NIH-funded research is conducted or partially conducted by a subrecipient, ASAM will take reasonable steps to ensure that subrecipient Investigator(s) comply with the federal regulations (42 CFR Part 50 Subpart F) including;

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the ASAM FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.
 - a. If subrecipient FCOI policy applies to subrecipient Investigators, then subrecipient must certify, as part of the agreement that their FCOI policy complies with the federal regulations (42 CFR Part 50 Subpart F)
 - b. The agreement will include specific time periods for the subrecipient to report all identified FCOI to ASAM whether the subrecipient Investigators comply to the subrecipient or ASAM's FCOI policy. Such time periods must be sufficient for ASAM to comply in a timely manner with its review, management, and reporting obligations
2. ASAM will provide all FCOI reports to NIH prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

Whenever ASAM implements a management plan for a FCOI, ASAM will monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS/NIH-funded research project.

H. Reporting Requirement to NIH

Prior to ASAM's expenditure of any funds under a PHS/NIH-funded research project, ASAM will provide to NIH a FCOI report regarding any Investigator SFI found by ASAM to be an FCOI, in accordance with the regulation. ASAM will also provide a FCOI report to NIH whenever an Investigator fails to timely disclose a SFI or whenever ASAM designated staff, for whatever reason, fail to timely review and/or properly identify a disclosed SFI but then subsequently review and determine that an FCOI exists. ASAM must report all identified FCOIs to NIH.

ASAM will submit an FCOI report to NIH within sixty (60) days after its determination that a FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the Institution during the award period.

Whenever an Investigator does not timely disclose a previously existing SFI or ASAM's

COO fails to timely review and/or properly identify a previously existing SFI regarding an ongoing PHS/NIH-funded research project, ASAM's COO will, within sixty (60) days:

1. Review the SFI
2. Determine whether it is related to the PHS/NIH-funded research;
3. Determine whether an FCOI exists. And if so, ASAM will implement, on at least an interim basis, a management plan that will specify the actions that have been or will be taken to manage such an FCOI going forward and submit an FCOI report to NIH.

In addition to the FCOI report, the Institution will, within one hundred and twenty (120) days of ASAM's determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, ASAM's COO will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, ASAM's COO will notify NIH officials promptly and submit a mitigation report that includes the key elements documented in the retrospective review, a description of the impact of the bias on the research project and ASAM's action plan or actions taken to eliminate or mitigate the effects of the bias. Thereafter, ASAM will submit FCOI reports annually.

ASAM will notify NIH promptly if an Investigator fails to comply with ASAM's FCOI policy or if the FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

For any FCOI previously reported ASAM will provide an annual FCOI report to NIH that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Annual FCOI reports will be submitted to NIH for the duration of the project period (including extensions with or without funds) at the same time as when ASAM is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in eRA Commons or submission of a NIH prior approval request, whichever is applicable.)

An annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module at the same time the annual progress report is submitted.

ASAM will send initial, annual (ongoing) and revised reports to NIH via the eRA Commons FCOI Module for ASAM and subrecipient Investigators. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to;

1. Project number
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used
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 (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
7. A description of how the financial interest relates to the PHS/NIH-funded research and why ASAM determined that the financial interest conflicts with such research
8. A description of the key elements of the ASAM's management plan
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance
 - f. Other information as needed.

When requested, ASAM will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether the disclosure resulted in the Institution's determination of an FCOI.

I. Maintenance of Records

All FCOI-related records, including Investigator's SFI disclosures, ASAM's review of, and response to, disclosures (whether resulting in a FCOI) and all actions taken under ASAM's FCOI policy or retroactive review, will be retained for at least 3 years from the date the final expenditure report is submitted to NIH or, where applicable, from other dates specified in 45 CFR 75.361

J. Violation of the FCOI Policy, Enforcement and Remedies

If the COO has reason to believe that an Investigator has failed to disclose an actual or potential FCOI, or the appearance of an FCOI, the COO will inform that Investigator of the basis for this belief and allow them an opportunity to respond.

After hearing the response of the Investigator, documentation of the response, and after initiating further investigation (as required), the COO, through the consultation and decision of the ASAM Ethics Committee and approval of the ASAM Executive Council and/or Board of Directors, in determining that the Investigator has failed to disclose an actual or possible FCOI, or the appearance of an FCOI, shall take appropriate administrative, disciplinary and/or corrective actions, to ensure Investigator compliance.

A retrospective review will be completed, within one hundred and twenty (120) days of the determination of noncompliance, of the Investigator's activities and the PHS/NIH-funded research project to determine whether any PHS/NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. All key elements of the retrospective review will be documented (as noted in section G Managing FCOI).

If bias is found ASAM will notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to NIH the report will be submitted as a "revised FCOI Report."

The mitigation report will include, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project and the ASAM's plan of action or actions taken to eliminate or mitigate the effect of the bias (as noted in section G Managing FCOI).

ASAM will modify or implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

In any case in which the Department of Health and Human Services (DHHS) determines that an PHS/NIH-funded research project, 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 in which there was a financial conflict of interest that was not managed or reported by the Institution as required by the regulation, ASAM will require the Investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

K. Subrecipient Investigator Requirements

As specified above, ASAM will incorporate language, as part of a written agreement with the subrecipient, that the ASAM's FCOI policy or the FCOI Policy of the subrecipient will apply

to the subrecipients Investigator(s). In applying the subrecipient FCOI policy the subrecipient must provide ASAM with certification that the subrecipient Investigator(s) is in compliance with 42 CFR Part 50 Subpart F and must submit all Investigator reported SFIs to ASAM within thirty (30) days of discovering or acquiring a new SFI and in sufficient time for ASAM to meet its FCOI reporting obligations. If a subrecipient does not have an FCOI Policy that complies with 42 CFR Part 50 Subpart F, a subrecipient Investigator must follow ASAM's FCOI Policy in all aspects.

L. Public Accessibility Requirements

ASAM maintains an up-to-date, written, enforced policy on FCOI that complies with 42 CFR Part 50 Subpart F, and makes the policy available via its publicly accessible website www.asam.org.

Prior to the expenditure of any funds under a PHS/NIH-funded research project, ASAM will ensure public accessibility; via ASAM website www.asam.org or by written response to any requester within 5 business days of a request or information concerning and SFI disclosed to ASAM that meet the following criteria.

1. The SFI was disclosed and is still maintained by ASAM senior/key personnel regarding a NIH-funded research project
2. ASAM determines that the SFI is related to the NIH-funded research; and
3. ASAM determines that the SFI is an FCOI.

The information that the ASAM makes available via written response will include, at a minimum, the following:

1. Investigator's name
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The information requested and provided by written response will include all updated information. The information that ASAM posts on its website or makes available on the website will be updated annually or within sixty (60) days of the:

1. Identification any additional SFI of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or
2. SFI of senior/key personnel new to the PHS-funded research project, related to the PHS/NIH-funded research and is a financial conflict of interest publicly accessible

(information will remain available for three (3) years from the date the information was most recently updated.)

To request information, please contact:

Carolyn C. Lanham, CAE
Chief Operating Officer
American Society of Addiction Medicine
clanham@asam.org

ASAM will submit its publicly accessible FCOI policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module).