



Financial Conflict of Interest Policy in Conduct of Research

AfaSci, Inc.

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Purpose

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest. This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

This policy is further to ensure appropriate management of any Financial Conflict of Interest (FCOI) as a result of an Investigator or senior personnel planning to participate in or currently participating in an NIH-funded project. AfaSci also provides all investigators and senior personnel who are applying for NIH funding to complete FCOI training prior to the proposal submission.

AfaSci requires Principal Investigators (PIs) and Key Personnel on a sponsored project to disclose a list of significant financial interests (SFIs) that could be reasonably expected to bias the design, conduct, or reporting of the project. All PIs and Co-PIs listed in a proposal for NIH funding must complete a disclosure form before expenses can be charged to an award.

1. Training requirements

AfaSci will conduct mandatory FCOI training. An Investigator must complete FCOI training prior to engaging in research related to any PHS-funded grant and at least every four years. The training is provided by the NIH, and the Investigator must submit the training completion form to AfaSci's Administrator.

- <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>

2. Disclosure, Review, Manage and Monitor Requirements

2.1 Disclosure



1. At time of application: Each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS-funded research must submit a financial conflict of interest disclosure form to AfaSci's Grant Administrator.

2. Updates:

- *Annual:* The Investigator, including subrecipient Investigators, if applicable, must submit an updated disclosure of SFI at least annually, during the period of the award, beginning with the anniversary date of the award.
- *Within 30 days:* The Investigator, including subrecipient Investigators, if applicable, must submit an updated disclosure of SFI within thirty days of discovering or acquiring a new SFI.

2.2 Review

The Grant Administrator of AfaSci will review all PHS disclosure forms and determine whether an Investigator's SFI is related to the PHS-funded research, i.e. whether the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. If it appears that the SFI is related to the PHS-funded research, the AfaSci's Management will determine whether a financial conflict of interest exists.

2.3 Management

FCOI policy specifies the time period(s) for investigators and the subrecipient to submit all Investigator disclosures of SFIs to AfaSci. AfaSci shall maintain records of all financial disclosures and all actions taken to resolve FCOI for at least 3 years from the date the final expenditures report is submitted to the federal agency, or until the resolution of any federal action involving those records, whichever is longer.

If a FCOI is identified, AfaSci's Management will determine whether the research can be undertaken. For cases that require action, a plan of action will be developed by AfaSci's Management. A draft of the plan of action will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.

2.4 Monitoring

Investigator compliance with plans of action will be monitored by AfaSci's Management. The frequency of monitoring will be dictated by sponsor/agency requirements and action plan provisions.

3. NIH Reporting Requirements



- Prior to AfaSci's expenditure of any funds under a PHS-funded research project, AfaSci is required to provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by AfaSci to be conflicting and ensure that AfaSci has implemented a management plan in accordance with the FCOI policy.
- For any SFI that AFASCI identifies as conflicting subsequent to its initial FCOI report during an ongoing PHS-funded research project, within sixty days AfaSci must provide to the PHS Awarding Component an FCOI report regarding the financial conflict of interest and ensure that AfaSci has implemented an FCOI management plan. If bias is found, AfaSci is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- For any FCOI previously reported by AfaSci regarding an ongoing PHS-funded research project, AfaSci shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project.

4. Enforcement Mechanisms, Remedies, and Noncompliance

Where an FCOI has been identified, the Grant Administrator will work with the personnel to develop a resolution plan to manage, reduce, or eliminate any actual or potential FCOI presented by a SFI. Possible approaches include, but are not limited to, the following:

- Public disclosure of SFIs;
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the related project or research;
- Severance of relationships that create actual or potential financial conflicts.

Whenever AfaSci identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the AfaSci, within 60 days the Grant Administrator will: review the SFI; determine whether it is related to the Investigator's institutional responsibilities; determine whether a FCOI exists. AfaSci's Management will review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

5. Retrospective Review Requirements

If an FCOI exists, to determine bias AfaSci will complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. AfaSci will implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.



Following retrospective review, if applicable, AfaSci will update/revise the existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report. If bias is found, AfaSci will:

- Notify the NIH promptly
- Submit a mitigation report through the FCOI Module
- Submit an annual FCOI report thereafter through the FCOI Module

6. Subrecipient Requirements

When AfaSci carries out any PHS-funded research through a subrecipient, AfaSci will ensure subrecipient monitoring and take reasonable steps to ensure that any subrecipient Investigator complies with PHS FCOI regulations by:

- Incorporating terms as part of a written agreement with the subrecipient that establish whether AfaSci's FCOI policy or the subrecipient's policy will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators are to comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy complies with the PHS FCOI regulations, and the agreement will specify the time period(s) for the subrecipient to report all identified FCOIs to AfaSci.

7. Public Accessibility Requirements for FCOIs identified for Senior/Key Personnel

AfaSci FCOI Policy is on its web site https://www.afasci.com/images/pdf/Afasci_FCOI23.pdf . Pursuant to PHS FCOI regulations, prior to spending any funds under a PHS-funded research project, AfaSci will ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any SFI interest disclosed to AfaSci that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel;
- AfaSci determines that the SFI is related to the PHS-funded research; and
- AfaSci determines that the SFI is a FCOI.

8. Maintenance of Records

AfaSci will maintain all records related to the implementation of this policy for at least three years after:

- The date of creation;
- The date of termination or completion of a research award or contract;
- The submission of the final expenditures report; or
- The date of final resolution of any investigation, audit, or similar action involving the records.



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9. Clinical Research

For research involving humans, special consideration and monitoring must be given to protect human subjects in research. Investigators with an identified FCOI or an SFI that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. Justification may be made including factors such as unique investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by AfaSci's Management. The AfaSci's Management must review the research with consideration given to the requirements of the action plan. The AfaSci's Management may require additional safeguards to be implemented and consult with the independent Safety Monitoring Committee.