

ActioX LLC Financial Conflict of Interest Policy

The objective of this policy is to outline the requirements and responsibilities related to identifying and managing financial conflicts of interest (FCOI) in order to protect the integrity of ActioX LLC's (Company) research and adhere to federal regulations.

Federal regulations mandate that institutions applying for or receiving research funding from federal agencies maintain a financial conflict of interest policy. The aim of this policy is to foster objectivity in research by creating standards that ensure no reasonable expectation exists that the design, execution, or reporting of research funded through federal grants, contracts, or cooperative agreements will be influenced by any conflicting financial interest of an Investigator (as defined below). This policy has been formulated to address and comply with specific federal agency requirements, as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

DEFINITIONS

The following definitions apply to this policy:

Company refers to ActioX LLC and all wholly owned subsidiaries.

Employee includes any individual who receives a W-2 from the Company and is considered employed by ActioX LLC. This encompasses part-time and full-time personnel. An Employee may also be designated as an Investigator and/or Senior/Key Personnel.

Employee's Company Responsibilities encompass an Employee's professional duties on behalf of the Company, which may consist of research, development, design, testing, research consultation, teaching, professional practice, Company committee memberships, and service on panels such as Company Review Boards or Data and Safety Monitoring Boards.

Grantor denotes any federal funding source, such as NIH, NSF, DOD, DOE, or other public/private partnerships where public funds are granted and utilized to support research conducted by an Investigator, Subrecipient, or Company for commercial purposes.

Investigator refers to the Project Director or Principal Investigator and any other individual, irrespective of title or position, who is responsible for the design, execution, or reporting of research funded by the Grantor or proposed for such funding. This may include collaborators or consultants, also known as **Subrecipients**.

Senior/Key Personnel includes the Program Manager or Principal Investigator and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the Grantor by the Company under the regulation.

Significant Financial Interest (SFI) constitutes a financial interest comprising one or more of the interests of the Employee (and those of the Employee's spouse and dependent children) that reasonably appear to be related to the Employee's Company Responsibilities. SFIs are defined below.

Subrecipient refers to any Investigator who is not considered an Employee, including collaborators such as subcontractors and consultants.

SIGNIFICANT FINANCIAL INTERESTS

Financial interest of the Employee (and those of the Employee's spouse and dependent children) that appears reasonably related to the Employee's Company Responsibilities.

I. Financial Interests considered as SFIs

a) Remuneration, Equity Interests, and Intellectual Property Rights

Concerning any publicly traded entity or non-publicly traded entity, a significant financial interest exists:

1. **Remuneration:** If the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000. For this definition, remuneration includes salary and any payment for services not identified as salary (e.g., consulting fees, honoraria, paid authorship);
2. **Equity:** When the Employee (or the Employee's spouse or dependent children) holds any equity interest, including any stock, stock option, or other ownership interest, that when aggregated, exceeds \$5,000 as of the disclosure date, as determined through reference to public prices or other reasonable measures of fair market value;
3. **Intellectual property rights** and interests (e.g., patents, copyrights): Upon receipt of income related to such rights and interests exceeding \$5,000.
4. **Foreign financial interests:** Any financial interests received from a foreign government or a foreign institution of higher education that are related to the Investigator's institutional responsibilities when such income exceeds the threshold for disclosure (e.g., in excess of \$5,000).

b) Reimbursed or Sponsored Travel

Employees must disclose any reimbursed or sponsored travel (i.e., paid on behalf of the Employee and not reimbursed to the Employee, so the exact monetary value may not be readily available) related to their research and job responsibilities at the Company. However, this disclosure requirement does not apply to travel 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 affiliated with an Institution of higher education.

II. Financial Interests not considered as SFIs

- a) Salary, stock options, intellectual property, retirement accounts, and/or royalty payments from the Company.
- b) Income from investment vehicles such as mutual funds, retirement accounts, and 401K plans, as long as the Employee does not directly control the investment decisions within the vehicle.
- c) Income from seminars, teaching engagements, or lectures 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 affiliated with an institution of higher education.
- d) Income from service on advisory committees or review panels 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 affiliated with an institution of higher education.
- e) Salary, royalties, or other payments from any public or nonpublic entity other than the Company that, when aggregated for the Employee and the Employee's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000.

Financial Conflict of Interest (FCOI) occurs when the Company's designated official(s) reasonably determine that an SFI could directly and significantly impact the design, conduct, or reporting of Grantor-funded research. The regulations set forth herein and in 45 CFR § 50.F serve as guidance to ascertain whether an SFI is considered an FCOI.

EMPLOYEE RESPONSIBILITIES

In accordance with federal legislation, guidelines, and ActioX LLC's Financial Conflict of Interest (FCOI) Policy, all Employees are required to perform the following duties:

1. Finish FCOI training within 30 days of beginning employment.
2. Renew FCOI training every four years at a minimum.
3. Complete training without delay if: a. ActioX updates its FCOI policy, impacting Investigator or Employee obligations, b. The Employee is deemed noncompliant with the policy or management plan.

4. Report any Significant Financial Interest(s) (SFI) using the SFI Disclosure form provided after finishing training.
5. Submit an FCOI Compliance Certification form and update your SFI Disclosure form(s) when necessary, at each of these occurrences: a) When submitting a new grant proposal with the Employee as Key Personnel; b) Upon receiving a new grant award or being assigned to a new project where the Employee is an Investigator; c) At least yearly from the last disclosure date; d) Within 30 days of identifying or acquiring a new SFI.

All training certificates and disclosure forms should be sent to ActioX's appointed official (identified at the end of this document). If there is any uncertainty about what constitutes an SFI or if you have inquiries about ActioX's FCOI policy, please get in touch with the appointed official. Employees should utilize the appointed official as a resource for their own SFI reporting and for reporting any perceived SFI or FCOI within ActioX. In the latter scenario, the appointed official will be in charge of follow-up.

The designated ActioX official will assess and determine if a potential financial conflict of interest exists. If so, the assigned FCOI committee will examine the potential conflict of interest and take measures to manage, minimize, and/or eliminate the conflict(s) as needed.

All Employees must adhere to ActioX's FCOI policy to mitigate, manage, and/or eradicate all possible financial conflicts of interest. If an FCOI is identified or noncompliance with the FCOI policy is discovered, the Employee must cooperate with the management plan established to address the FCOI or noncompliance. ActioX may seek advice from external legal counsel with FCOI expertise for assessing potential FCOI and FCOI management plans. Confidentiality: Except as mandated by law and federal regulations, the disclosed information will remain confidential and only be shared internally on a need-to-know basis with those evaluating the FCOI and/or implementing an FCOI management plan. However, ActioX is obligated to report the presence of actual or potential conflicts of interest to specific federal agencies. In particular, the NIH (PHS) requires companies to report to the PHS any conflicting interests and ensure that the interest has been managed, reduced, or eliminated. The NSF mandates that only conflicts that have not been managed, reduced, or eliminated before spending funds under an award be reported to the NSF. Furthermore, some information is subject to federally required public accessibility, as outlined in this policy under Public Accessibility.

Employee Forms: Attached to this FCOI policy are four forms for Employees to fulfill their obligations:

1. FCOI POLICY ACKNOWLEDGMENT;
2. FCOI TRAINING ACKNOWLEDGMENT;
3. FCOI COMPLIANCE CERTIFICATION;
4. SFI DISCLOSURE FORM.

COMPANY OBLIGATIONS

Policy Creation

Federal Regulations mandate that ActioX LLC develop, maintain, and enforce a financial conflicts of interest policy to identify and manage any financial conflicts of interest in ongoing research programs. ActioX LLC is required to inform all Employees of this policy and properly train and enforce this FCOI policy for all Employees.

ActioX LLC FCOI Policy and FCOI Training

Every new Employee must be provided a copy of this policy and training materials within 5 business days of their start date. The Employee must complete training and submit the training certificate to the designated ActioX LLC official within 10 business days. The Employee must also sign that they have received, read, and understood the ActioX LLC FCOI policy within 10 business days of their start date. These certificates must be filed in the Employee's record until updated certificates are received.

Training must be completed, and a new training certificate must be filed at the following times:

1. Within 30 days of start date;
2. At least every four years;
3. If the Employee is ever found noncompliant with the policy or management plan.

A training presentation prepared by the NIH covering the basics of federal regulations pertaining to financial conflict of interest and federal grants can be found at:

- <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Review of this presentation and completion of the certificate will serve as the ActioX LLC training. The Employee must recertify that they have received, read, and understood the ActioX LLC FCOI policy whenever Employees are notified of a revision that affects employee responsibilities.

Disclosures, Review, Management, and Monitoring SFI

Before engaging in government-sponsored research, the CEO must grant advance approval. ActioX LLC must collect FCOI compliance certification and any corresponding SFI disclosure form(s) from every Employee after completing training and within 30 days of employment commencement. A separate SFI disclosure form (attached) is required for each entity in/with which the Employee holds an SFI. It is the responsibility of the designated ActioX LLC official to ensure they receive the disclosure forms from each Employee upon the respective due dates as designated above.

The disclosure forms should be collected by the designated ActioX LLC official and reviewed for potential conflict of interest within ten (10) business days of receipt. The designated official must sign the original SFI disclosure form to signify their review. If the designated ActioX LLC official becomes aware of a potential FCOI, they will bring it to the

attention of the CEO. At that time, a review committee will be selected by the designated official and CEO, consisting of at least 2 additional unbiased personnel (such as Employees at the VP or Director level) to review the SFI.

The review committee (designated official and/or CEO and 2 additional committee members) will meet to discuss and determine whether the SFI represents an FCOI within fifteen (15) business days from the submission of the disclosure form. If it is determined that an FCOI exists, a management plan must be developed by the review committee to report, manage, and/or eliminate the conflict of interest within sixty (60) days. This management plan must be shared with the Employee, Investigator, or Subrecipient, along with a list of tasks and/or sanctions to resolve the conflict of interest. The review committee must meet at least monthly to ensure the management plan has been appropriately executed until the conflict is being managed or resolved according to the management plan.

ActioX LLC may consult outside legal counsel with FCOI expertise for the evaluation of potential FCOI and FCOI management plans. Management plans may include public disclosures of FCOI at each public presentation of the results or research, in conformance with requirements of the organizers of the public presentation. The company will adhere to the federal agency requests, providing data concerning potential conflicts of interest and the strategies implemented to manage, reduce, or eliminate them.

Reporting

ActioX LLC is committed to certifying in each application for research funding from federal agencies the existence of this policy and to identify any existing conflicts of interest, assuring that they have been managed, reduced, and/or eliminated upon request of the Grantor. ActioX LLC also agrees to report any conflicting interests (FCOIs) to the appropriate federal agency through its required procedure at the following time points:

1. Prior to expenditure of any grant funds;
2. Within sixty (60) days of any new conflicts of interest that become apparent after the initial report to the relevant federal agency;
3. Within sixty (60) days of the identification of a new Employee or Investigator participating in the research project;
4. At any additional time point requested by the Grantor;
5. Following a retrospective review to make appropriate changes to the previously submitted report.

If applicable, a mitigation report must be filed when bias is found as a result of a retrospective review. ActioX LLC is required to submit all FCOI reports to the Grantor

through the Grantor's required procedure. For the NIH, this is through the eRA Commons FCOI Module.

Maintenance of Records

ActioX LLC shall keep all FCOI-related documents, including the review and response to each SFI disclosure, on file for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361.

Enforcement Mechanisms, Remedies, and Noncompliance

Federal regulations require ActioX LLC to impose sanctions where appropriate. ActioX LLC maintains the right to impose sanctions on Employees for failure to disclose SFIs within the time frames specified in this policy and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals, change of work responsibilities while delinquent SFI and/or FCOIs are evaluated, and other disciplinary actions up to and including dismissal.

If it has been determined that an Employee, Investigator, or ActioX LLC is in noncompliance with this policy (e.g., SFIs not disclosed, reviewed, or managed in a timely or appropriate manner), ActioX LLC must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the SFI disclosure review committee as designated by the President and the designated ActioX LLC official.

A retrospective review is required under the following circumstances:

1. Failure to disclose a significant financial interest in a timely manner.
2. Inadequate review or management of an existing significant financial interest.
3. Failure to comply with an existing management plan for a significant financial interest.

The retrospective review should include the following documentation:

1. Project number, title, and Principal Investigator's name.
2. Name of the Investigator or Employee with the noncompliant significant financial interest.
3. Reason(s) for the retrospective review (e.g., failure to disclose, inadequate review, or noncompliance with management plan).
4. Detailed methodology used for the retrospective review.
5. Findings and conclusions of the review.

The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, ActioX LLC must immediately notify the Grantor by submitting a mitigation report. The mitigation report should include:

1. Description of the impact of the bias on the research project.

2. Plan of action(s) to eliminate or mitigate the effect of the bias.

ActioX LLC should refer to NIH's FAQ I.1. at Frequently Asked Questions (FAQs) | grants.nih.gov and I.2. at Frequently Asked Questions (FAQs) | grants.nih.gov for further guidance on retrospective review requirements and documentation.

ActioX LLC must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations for a project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, ActioX LLC must require the Employee or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.

Subrecipient Requirements

If a Subrecipient is not employed by ActioX LLC, they may comply with their institution's FCOI policy, provided that their institution has a suitable policy in place and that they supply ActioX LLC with the necessary disclosure information to meet all reporting obligations and deadlines. Prior to the Subrecipient's participation in the research project, they must certify that their institutional FCOI policy complies with regulations. If the Subrecipient's institution does not have a suitable FCOI policy in place, they shall adhere to this policy set forth for Investigators of ActioX.

Public Accessibility

This FCOI policy is publicly available on our website at <https://actiox.me>. Information regarding FCOIs must be accessible upon written request within five (5) business days. Requests can be made by email at info@actiox.me with the subject line "FCOI information request."

Requests for information that meet these three criteria in federal regulations will be processed:

1. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the government grant-funded research project identified by ActioX LLC in the grant application, progress report, or any other required report submitted to the Grantor;
2. ActioX LLC has determined that the Significant Financial Interest is related to Grantor-funded research; and
3. ActioX LLC has determined that the Significant Financial Interest is a Financial Conflict of Interest.

ActioX LLC is required to submit to the Grantor upon request all records pertinent to compliance with the public accessibility regulations.

Resources

1. http://grants.nih.gov/grants/policy/coi/coi_faqs.htm (frequently asked questions)
2. <http://grants.nih.gov/grants/policy/coi/index.htm> (policy and guidance)
3. FCOICompliance@mail.nih.gov

FCOI POLICY ACKNOWLEDGEMENT
MANDATORY FOR ALL EMPLOYEES

I acknowledge that:

- ActioX LLC. has provided me access to the Company FCOI policy.
- I have read, understood, and had an opportunity to ask questions concerning this FCOI policy.

Check one:

- First reading of FCOI Policy as new employee
- First reading of FCOI Policy as Policy is introduced
- Repeated reading of FCOI Policy as Policy is updated

Print Name: _____

Signed: _____ Date: _____

FCOI TRAINING ACKNOWLEDGEMENT (MANDATORY FOR ALL EMPLOYEES)

I acknowledge that:

- I have undergone the required FCOI training mandated in the current FCOI policy.
- I have attached the appropriate training certificate(s)

Check one:

- First training as new employee
- First training as FCOI Policy is introduced
- Repeated training every four years
- Repeat training due to return to compliance with FCOI policy or an FCOI management plan

Print Name: _____

Signed: _____ Date: _____

FCOI COMPLIANCE CERTIFICATION

SCREENING QUESTIONNAIRE FOR SFIs		
Please check YES or NO for each of the following:	Yes	No
During the past twelve months , did you, your spouse, registered domestic partner, or your dependent children receive aggregated compensation – monetary or otherwise (e.g., consulting fees, honoraria, speaking fees, stipends, dividends, ownership interest, equity interest, stock, stock options and gifts)—exceeding \$5,000 in value from an external entity operating in areas relating to your responsibilities ?		
During the past twelve months did you, your spouse, registered domestic partner or your dependent children own any equity interest including any stock, stock option, or other ownership interest, that when aggregated, exceeds \$5,000 as of the date of the disclosure as determined through reference to public prices or other reasonable measures of fair market value related to your Company responsibilities		
During the past twelve months , did you, your spouse, registered domestic partner, or your dependent children receive income exceeding \$5,000 related to any interests or rights in intellectual property from an external entity related to your Company responsibilities ?		
During the past twelve months , did you, your spouse, registered domestic partner, or your dependent children receive aggregated compensation or other financial interests exceeding \$5,000 from a foreign government or a foreign institution of higher education related to your institutional responsibilities ?		
During the past twelve months or in the next twelve months , did you participate in/do you plan to participate in any travel that was reimbursed or sponsored by an external entity operating in areas relating to your responsibilities ? Do not report travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.		

Check one:

Based on the Company FCOI policy and the questionnaire above:

I **DO NOT** have new SFIs to report or existing SFIs to update.

I **DO** have SFI(s) to report or update which are attached.

Check one:

Occasion for recertifying my SFI disclosures are up to date:

Initial (start of FCOI policy)

Initial (new employee)

Submittal of grant application as Key Personnel: proposal # _____

New grant award or assignment to new project: grant # _____

Annual

New SFI to report

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name: _____

Signed: _____ Date: _____

SFI DISCLOSURE FORM (one ENTITY per form)

Entity

Entity type

(e.g., energy, biomedical, service provider, or other)

Check one:

List an SFI

Update/edit an SFI

Delist an SFI

1) Employee Significant Financial Interest as defined in FCOI policy
Include type of interest (renumeration, equity, intellectual property, travel), dollar amount, dates, and other details:

2) ALL open Federal Grants where employee is an investigator:

3) Explain any potential relationship between Employee, Entity and any Federal Grant for which employee is an Investigator: (e.g., vendor, subcontractor, potential investor)

4) If delisting an SFI, state reason: (e.g., equity sold)

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name: _____

Signed: _____ Date: _____

SFI Review (Designated ActioX LLC Official)

Check one:

SFI is not deemed a FCOI with respect to any applicable grants

SFI may be an FCOI with respect to grant(s) _____ and has been referred to FCOI committee for review on or before _____

Print Name: _____

Signed: _____ Date: _____