



AIQ Solutions Financial Conflict of Interest (FCOI) Policy

To promote compliance with the FCOI regulations, AIQ Solutions (AIQ) has adopted the following FCOI policy.

Training Requirements

Each investigator on a grant that is funded by the Federal Health and Human Services Department shall be informed of the terms of this FCOI policy, so that they are aware of their responsibilities under the policy. An "investigator" is defined (for the purposes of this policy) as "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."

Each Investigator, including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

AIQ will utilize some of the resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page (<http://grants.nih.gov/grants/policy/coi/>) to satisfy some of the training requirements. AIQ refers investigators to the NIH tutorial on FCOI, located at https://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf. AIQ will also provide additional training regarding individual Investigator's responsibilities for disclosure of Significant Financial Interests and of AIQ's specific policy on FCOI.

Disclosure, Review and Monitoring Requirements

Each investigator is required to disclose their Significant Financial Interests (SFIs) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI. "SFI" is defined as the interest of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities 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) in AIQ. However, SFI specifically does NOT include salary, royalties, or other remuneration paid by AIQ to the Investigator if the Investigator is currently employed or otherwise appointed by AIQ, including intellectual property rights assigned to AIQ and agreements to share in royalties related to such rights; any ownership interest in AIQ held by the Investigator, (allowable because AIQ is a commercial/for-profit organization); 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; 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 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.

Investigators are required to disclose their SFI's at the following times:

- No later than at the time of application for PHS/NIH-funded research.
- At least annually during the period of the award.
- Within thirty (30) days of discovering or acquiring a new SFI.

AIQ shall designate an institutional official(s) to solicit and review disclosures of SFIs of the Investigator

(and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI. AIQ shall provide adequate guidelines consistent with the regulation for the institutional official(s) to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI. An SFI is related to PHS/NIH-funded research when the Institution through its designated official(s), reasonably determines that the SFI:

- could be affected by the PHS/NIH-funded research; or
- 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. An FCOI exists when the Institution, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. AIQ may manage an Investigator's FCOI through any of the following methods:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.;
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

AIQ shall also require its designated official(s), prior to Institution's expenditure of funds, to review all Investigator SFI disclosures, determine if any SFIs relate to PHS/NIH-funded research, and then determine if an FCOI exists (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research). When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, AIQ's designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, 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 FCOI. Whenever an Institution identifies an SFI that was not timely disclosed by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward. This applies to FCOIs of a subrecipient Investigator, if applicable.

Reporting Requirements to NIH

AIQ's designated official shall send initial, annual (i.e., ongoing) and revised FCOI reports, including all the following information:

- Project number;
- Project title;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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;
- A description of how the financial interest relates to the NIH-funded research and why the Institution

determined that the financial interest conflicts with such research;

- A description of the key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

These reports shall be provided to the NIH or other granting agency: prior to the expenditure of funds; within sixty (60) days of identification for an Investigator who is newly participating in the project; within sixty (60) days for new, or newly identified, FCOIs for existing Investigators; at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and, after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review. AIQ will also promptly notify the NIH if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation or at any time if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research. AIQ shall notify the NIH promptly and take corrective action for noncompliance with this policy or the management plan.

Maintenance of Records

AIQ shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and AIQ's review of, and response, to such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under this policy or retrospective review, if applicable, for at least three (3) years from the date the final report is submitted to the PHS (NIH).

Enforcement Mechanisms and Remedies and Noncompliance

AIQ provides the following mechanism for employee sanctions to ensure Investigator compliance:

- First offence: the employee shall receive a letter of reprimand from management.
- Second offence: the employee shall receive a restriction on the use of funds for the project.
- Third or subsequent offence: the employee shall be forbidden from participating in the project at question.

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI;
- Failure by AIQ to review or manage such a FCOI; or
- Failure by the Investigator to comply with a FCOI management plan.

AIQ shall, within 120 days of the determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any 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. If it is determined that the research was biased in any way, AIQ shall document this as if it was reporting it to the NIH (see above) except that the report shall also include

- The reasons for the retrospective review;
- A detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
- The findings of the review; and,
- The conclusions of the review.

In any case in which the Department of HHS or the NIH determines that a PHS/NIH-funded research project of clinical research 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 with an FCOI that was not managed or reported by AIQ as required, AIQ shall 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 that discloses the FCOI.

Subrecipient Requirements

AIQ is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOI's for subrecipient Investigators to the NIH. AIQ shall incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

Subrecipient Institutions who rely on their own FCOI policies must report identified financial conflicts of interests to AIQ in sufficient time to allow AIQ to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with AIQ's policy must submit all Investigator disclosures of SFI's to the awardee in sufficient time to allow AIQ to review, manage and report identified FCOIs to the NIH.

AIQ acknowledges that it is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOI's to the NIH. It will do by obtaining a certification from the subrecipient that its FCOI policy complies with the regulation.

Public Accessibility Requirements

AIQ shall make this FCOI policy publicly accessible by posting it on its public Web site. The publicly accessible information will be posted at <https://www.aig-solutons.com>. This policy shall be updated, at least annually. It will also be updated within sixty (60) days of a newly identified FCOI and shall remain available for three (3) years from the date the information was most recently updated.

“Significant Financial Interest” (SFI) Disclosure Form

The financial disclosure form used for “Investigators” to disclose their SFIs to the Institution's designated official(s) for a determination of FCOI should include at a minimum the following information:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure requirement that is consistent with the institution's definition of SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of equity interest as of the date of disclosure
- Provide for disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests
- Provide for the disclosure of reimbursed or sponsored travel that includes at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Clarify that disclosure is required for all financial interests received from a foreign institution of higher education or the government of another country.
- The value of the SFI.
- Provide a distinction whether the SFI is from a publicly traded or non-publicly traded entity.
- Provide a description of the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Provide an indication whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness. Some information to consider:
 - The institution's designated official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research).
 - Per the preamble in the [Final Rule](#) (page 53261), “significantly” means “...the financial interest would have a ‘material effect on the research’...”.