



QSIMULATE

# **Financial Conflict of Interest Policy**

## Purpose

The purpose of this policy is to establish standards such that the design, conduct, and reporting of NIH-funded research (grants and cooperative agreements) is free from bias resulting from any Investigator's conflicting financial interest (FCOI).

## Policy

### 1. Definitions

#### 1a. *Investigator:*

The Principal Investigator and any other person, regardless of title or position, are responsible for the purpose, design, conduct, or reporting of a federally funded project.

#### 1b. *Significant Financial Interest (SFI):*

A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities.

- With regard to any publicly traded entity, 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;
- With regard to any non-publicly traded entity, an SFI 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);
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests when aggregated, exceeds \$5,000.
- Travel reimbursement or sponsorship that is not otherwise disclosed in current and pending or other support disclosures when aggregated, exceeds \$5,000 . (except travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency; another U.S. institution of higher education; a U.S. academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education).

SFIs do NOT include:

- Salary, royalties, or other remuneration paid by the QSimulate to the Investigator if the Investigator is currently employed or otherwise appointed by QSimulate, including intellectual property rights assigned to the non-Federal entity and agreements to share in royalties related to such rights.
- Any ownership interest in QSimulate held by the Investigator.
- 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 of the United States, a domestic institution of higher education, or a domestic research institute that is affiliated with a domestic Institution of higher education.
- Income from service on advisory committees or review panels for a federal, state, or local government agency of the United States, a domestic institution of higher education, or a domestic research institute that is affiliated with a domestic institution of higher education.

**1c. Financial Conflicts of Interest (FCOI):**

- A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

**1d. Senior/key personnel:**

- Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the QSimulate in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution. This term is defined only as it relates to the public accessibility requirements described under section 8 of this policy

**1e. Institutional Responsibilities:**

- Institutional responsibilities are the professional activities an investigator performs on behalf of QSimulate (e.g. research, or scientific development).

## **2. Training Requirements**

**2a.** QSimulate will inform each Investigator of

- QSimulate's Financial Conflict of Interest Policy
- Investigator's disclosure responsibilities of all foreign and domestic SFIs
- Federal regulation

**2b.** All Investigators must complete training (1) prior to engaging in NIH-funded projects; (2) at least every four years; and (3) immediately under the designated circumstances:

- 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.

### 3. Disclosure, Review and Monitoring Requirements

**3a.** The Head of HR is the designated official to solicit and review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children). Head of HR as the designated official will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

**3b.** An SFI is related to PHS/NIH-funded research when QSimulate reasonably determines that the SFI meets one of the following criteria.

- Could be affected by the PHS/NIH-funded research.
- Is in an entity whose financial interest could be affected by the research.

Note the Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.

**3c.** All Investigators are required to disclose all foreign and domestic SFIs to QSimulate that meet the criteria for an SFI as outlined in this policy.

**3d.** SFIs of the Investigator (and/or their spouse or dependents) must be disclosed:

- No later than at the time of application for NIH-funded research
- At least annually during the period of the award
- Within thirty days of discovering or acquiring new SFI

**3e.** Disclosures are reported using the [Financial Disclosure Form](#).

**3f.** Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests
- Appointment of an independent monitor to ensure that the research is free from bias resulting from FCOI.
- Modification of the research plan
- Change of personnel or personnel responsibilities
- Reduction or elimination of the financial interest

**3g.** The designated official is required, prior to QSimulate's expenditure of funds to

- Review all Investigator SFI disclosures
- Determine if any SFIs relate to the Investigator's NIH-funded research
- Determine if a financial conflict of interest exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)

- Develop and implement a management plan to manage the financial conflict of interest(s)

**3h.** When an Investigator who is new to participating in the research project discloses an SFI or when an existing Investigator discloses a new SFI, the designated official will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research. The designated official will then 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 the FCOI.

**3i.** Whenever QSimulate identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by QSimulate during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's 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 the FCOI going forward.

**3j.** The designated official will take necessary actions to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

## 4. Reporting Requirements

**4a.** QSimulate will send initial, annual, and revised FCOI reports for QSimulate's Investigators and those of its subrecipients, if applicable, including all required information as stated below:

- Prior to the expenditure of funds.
- Within sixty days of identification for an Investigator who is newly participating in the project.
- Within sixty days for new, or newly identified, FCOIs for existing Investigators.
- At least annually, 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.
- After a retrospective review update a previously submitted report, if new information is discovered following the completion of the review.

**4b.** Based on the results of a retrospective review, notify the NIH promptly if bias is found with the design, conduct, or reporting of federally funded research and submit a mitigation report.

**4c.** QSimulate will submit the required mitigation reports to the NIH. Mitigation reports at a minimum must include a description of the impact of the bias on the research project and QSimulate's plan of action or actions taken to eliminate or mitigate the effect of the bias.

**4d.** To ensure compliance with retrospective review and bias mitigation reporting requirements, the policy and/or procedures should include all of the key elements documented in the retrospective review as well as the elements of a mitigation report that must be submitted to NIH.

**4e.** If noncompliance is found QSimulate will promptly notify NIH and take corrective action for noncompliance.

## 5. Management of Records

**5a.** QSimulate shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and QSimulate's review of, and response to, such disclosures (whether or not a disclosure resulted in QSimulate's determination of a financial conflict of interest) and all actions under QSimulate's policy or retrospective review, if applicable,

- For at least three (3) years from the date the final expenditures report is submitted
- Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations

## 6. Enforcement and Noncompliance

**6a.** The Head of HR will enforce this policy to each Investigator as the designated official. The CEO will ultimately be responsible for enforcement and compliance with this policy.

**6b.** If an FCOI is not identified or managed in a timely manner the designated official will complete a retrospective review within 120 days of the noncompliance. Examples of this include:

- Failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a financial conflict of interest.
- Failure by the Institution to review or manage such a financial conflict of interest.
- Failure by the Investigator to comply with the financial conflict of interest management plan.

**6c.** Retrospective reviews will be documented, which include:

- Project number
- Project title
- Project PD/PI
- Name of the Investigator with a FCOI
- Name of the entity with which the Investigator has an FCOI
- Reason for the retrospective review
- Detailed methodology used for the retrospective review
- Findings of the review
- Conclusion of the review

**6d.** An 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 QSimulate as required by the regulation, QSimulate shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentation.

## 7. Subrecipient Requirements

**7a.** Collaborators, from institutions or organizations who share responsibility for the design, conduct, or reporting of research results, must comply with the policies and procedures of their own institution/organization relating to conflict of interest disclosure, management, and enforcement. Compliance among project collaborators will be ensured by a written (NIH subaward/consortium) agreement between QSimulate and project collaborators.

**7b.** If there is a subrecipient included in an NIH-funded project, QSimulate establishes, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.

- QSimulate obtains a certification from the subrecipient that its FCOI policy complies with the regulation
- The written subrecipient agreement shall include a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows QSimulate to report identified FCOIs to the NIH or a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

## 8. Public Accessibility

**8a.** This policy shall be made accessible on QSimulate's public website.

**8b.** Information concerning identified FCOIs held by senior/key personnel will be publicly accessible through QSimulate's public website.

**8c.** The publicly accessible policy will be updated at least annually or within sixty days of a newly identified FCOI for senior/key personnel.

**8d.** The publicly accessible policy shall remain available for three years from the date the information was most recently updated.