

## **Financial Conflict of Interest (FCOI) Policy of Quanterix Corporation**

### **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 research at Quanterix Corporation (the Institution), and to meet or exceed the federal regulations on Significant Financial Interests (SFI) of our employees.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised regulations 42 CFR part 50 subpart F "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule." ("FCOI Regulation"), provided here <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under Public Health Service (PHS) and National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

### **SUMMARY OF PROCESS**

Significant Financial Interests (SFI) (as defined below) shall be disclosed on the SFI Disclosure Form (see Appendix) by an Investigator requesting government-sponsored funds for a research project, or by an Investigator when a Significant Financial Interest arises during the course of research. Discovery or acquisition of a new SFI must be disclosed to the Institution within 30 days. Regardless of whether an SFI exists, all Investigators and Key Personnel (each as defined below) are required to submit an SFI Disclosure Form annually. It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or during an award.

The SFI Disclosure Form and supporting materials are sent to the FCOI Officer (as defined below) for review. The FCOI Officer will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the Signing Official (SO) is required prior to engaging in government-sponsored research. An SFI review must be completed before any expenses are incurred under an award. Annual updates are required of all Investigators participating in NIH-funded research. Any Investigator who has acquired a new or increased financial interest during a research project shall report it immediately to the FCOI Officer. Annual updates and newly acquired interests are reported using the SFI Disclosure Form.

## **KEY DEFINITIONS**

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI.

*Investigator*: means the Project Director (PD), Principal Investigator (PI), Key Personnel, and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

*Institutional responsibilities*: means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

*FCOI Officer*: means the individual designated by the Institution to oversee this policy, including solicitation and review of SFI Disclosure Forms, or such individual's designee. This individual also files reports to the NIH via the FCOI module of ERA Commons.

*Financial interest*: means anything of monetary value, whether or not the value is readily ascertainable.

*Financial conflict of interest (FCOI)*: means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

*Management Plan*: means a plan put in place between the Institution and an Investigator with a financial conflict of interest. The terms, conditions, and restrictions of this plan ensure compliance with this policy, and manage, reduce, or eliminate any actual or potential conflict of interest. These plans ensure that the design, conduct, and reporting of research will be free from bias.

*Key Personnel*: means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution.

*Significant Financial Interest (SFI)*:

(1) A financial interest consisting of one or more of the following interests 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:

- (i) 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; (ii) 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 (iii) intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such 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 excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Institution directly (i.e., the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Institution relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination, and duration. The Institution is required to determine if additional information is required (e.g., monetary value) and whether the travel constitutes a FCOI with NIH-funded research.

(3) SFI does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution; (ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; (iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; (iv) 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; (v) 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 (vi) income from service on advisory committees or review panels for a federal, state or local government agency, 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.

*Signing Official (SO):* An SO has institutional authority to legally bind the institution in grant-administration matters by providing signature approval on grant application submissions. The SO also submits to the NIH the FOCI policy and policy updates via the FCOI module on ERA Commons.

## **PROCEDURES**

*A. Identification of Persons Required to Disclose a Significant Financial Interest:* It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who

have an SFI requiring disclosure under this policy and to ensure that an SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

*B. Submission and Review of SFI Disclosure Form:* Every individual having an SFI requiring disclosure under this policy shall prepare a fully completed SFI Disclosure Form (see Appendix) that shall be submitted to the FCOI Officer. An initial review of the SFI Disclosure Form will be conducted by the FCOI Officer to determine whether a potential for conflict of interest with PHS/NIH-funded research exists. If it is determined that there is a potential FCOI (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research), then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken to manage, reduce, or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests
- Review of research protocols by independent reviewers
- Monitoring of research by independent reviewers
- Modification of research plan
- Disqualification from participation in all or a portion of the research funded
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the FCOI Officer. Compliance of the management plan shall be monitored by the FCOI Officer.

*C. Annual Reporting and After-Acquired Significant Financial Interests:* All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the FCOI Officer.

When an Investigator who is new to participating in the research project or when an existing Investigator acquires a new SFI, an SFI Disclosure Form will be submitted and reviewed within sixty (60) days. The FCOI Officer will 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 the Institution identifies an SFI that was not 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 FCOI Officer shall within sixty (60) days review the disclosure of SFI, 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.

*D. Noncompliance of FCOI Policy:* Investigators are expected to comply fully and promptly with this policy. Whenever an Investigator has violated this policy—including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan—or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, the FCOI Officer shall make recommendations to the Chief Executive Officer (CEO) regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, the Institution shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved. The Institution will notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and 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.

In addition, the Institution will complete a retrospective review within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

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

The retrospective review will include the following key elements: project/NIH grant number; project title; PD/PI name; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; reasons for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed); and, findings and conclusions of the review.

The Institution will ensure that in any case in which the Department of Health and Human Services 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 the Institution as required by the regulation, the Institution 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.

E. Record Keeping: The FCOI Officer of the Institution will maintain for three (3) years from the date the final expenditure report is submitted to the NIH, or, where applicable, from other dates specified in 45 CFR 75.361 for different situations:

- i. All FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether a disclosure resulted in the Institution's determination of a financial conflict of interest);
- ii. All actions under the Institution's policy or retrospective review; and
- iii. Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest.

F. Sub-award Recipient Requirements: Sub-award recipients of funding in which the Institution is the primary awardee must comply with this policy. The Institution will establish, via sub-contract agreements, that the sub-award recipient will either follow the FCOI policy of the awardee Institution or the institutional FCOI policy of the subrecipient. In the case of a sub-award recipient following their own FCOI policy, the Institution will obtain from the sub-award recipient documentation that its FCOI policy complies with the regulation.

The sub-contract agreements will require that if an SFI is identified by the sub-award recipient, they are required to notify the FCOI Officer of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

G. Federal Reporting: The FCOI Officer is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients. The following reports are required by the NIH:

- i. Initial report: Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator SFI found by the Institution to be a financial conflict of interest in accordance with the regulation.
- ii. During on-going NIH-funded research projects: The Institution shall submit an FCOI report within 60 days after its determination that a new FCOI exists or within sixty (60) days of identification for an Investigator who is newly participating in the project. If a FCOI for an existing Investigator was not disclosed timely, the Institution shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
- iii. Annual FCOI report: For any FCOI previously reported to the NIH, the Institution shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. The report will be submitted 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.

*H. Public Access to FCOI policy and FCOIs:* This policy will be posted on the Institution's public website. The Institution will make available information concerning identified FCOIs held by Key Personnel (as defined by the regulation, not the NIH Grants Policy Statement) publicly accessible prior to the expenditure of funds. This publicly accessible information will:

- i. Include the minimum elements as provided in the regulation
- ii. Be made available within five (5) business days of a written request
- iii. Remain available for three (3) years from the date the information was most recently updated

The responses provided in written requests will contain the most up to date information.

## **TRAINING**

Each Investigator must complete FCOI training:

- a) Prior to engaging in research related to any PHS/NIH-funded grant
- b) At least every four (4) years
- c) Immediately, if:
  - i. Institution revises its FCOI policy that affects requirements of Investigators
  - ii. An Investigator is new to an Institution
  - iii. An Investigator is not in compliance with the policy or management plan

The NIH Financial Conflict of Interest training is accessible online at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> . Upon completion of the training, a certificate of completion must be turned into the FCOI Officer. You should retain a copy for your records.

**Appendix:**  
**Significant Financial Interest (SFI) Disclosure Form**

**Significant Financial Interest (SFI) Disclosure Form**

Persons completing this form are expected to have read and understood the Financial Conflict of Interest (FCOI) Policy of Quanterix Corporation. If you have any questions regarding that policy, contact the FCOI Officer prior to signing this document.

1. Do you, your spouse, or dependent children have a “significant financial interest (SFI)” (as defined on the Financial Conflict of Interest (FCOI) Policy of Quanterix Corporation) that would reasonably appear to be affected by your “Research”?

Yes  No

If yes, please describe in the space provided on page 2 of this form the nature and extent of your/their affiliation.

2. Do you, your spouse, or dependent children have a “significant financial interest” in any business or legal entity whose financial interests would reasonably appear to be affected by this covered “Research”?

Yes  No

If yes, please describe in the space provided on page 2 of this form the nature and extent of your/their affiliation.

I certify that:

I have read the Financial Conflict of Interest (FCOI) Policy of Quanterix Corporation.

I have made all required financial disclosures.

(Project Director or Principal Investigator only) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature \_\_\_\_\_ Date: \_\_\_\_\_

Typed/Printed name: \_\_\_\_\_

Disclosure Type:

First time

Annual update

Project specific: Project title: \_\_\_\_\_ Funding Agency: \_\_\_\_\_

