

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

QScint Imaging Solutions LLC

www.qscint.com

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1 SCOPE

The scope of this document is any work engaged in by QScint Imaging Solutions LLC (“QScint”) funded by US Public Health Service grants wherein QScint or its subsidiaries are the recipient(s) of public funding.

2 PURPOSE

The purpose of this document is to establish QScint’s policy for Financial Conflict of Interest (FCOI) and to prevent potential bias resulting from any FCOI by individuals who have direct influence in the allocation and use of public funding in the conduct of research. The FCOI policy is intended to align with the requirements in regulation 42 CFR Part 50 – Subpart F with the goal of promoting objectivity and transparency in research.

3 TERMS AND ABBREVIATIONS

FCOI : A Financial Conflict of Interest. A financial conflict of interest exists when the institution's designated official(s) reasonably determines that an Investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The institution is required to review each Investigator SFI disclosure to determine if a SFI:

1. is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research)
and
2. could directly and significantly affect the design, conduct, or reporting of the NIH-funded research

FCOI Manager : The QScint employee designated as the official for managing the FCOI process related to a PHS grant and who is responsible for ensuring that this Policy is followed for the scope of the Research Project.

Financial Interest : Anything which has readily ascertainable monetary value.

Investigator(s) : The PD/PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include (for example) collaborators or consultants. Includes Investigators who plan to participate in, or who do participate in NIH-funded research.

Management Committee : QScint’s Management Committee responsible for taking all executive decisions and actions for the company and oversee its processes.

NIH : National Institutes of Health

PD : Project Director

PHS : the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)

PI : Principal Investigator

Research Project : The PHS-funded work to which this Policy is being applied.

- 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. 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;
 - 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), a significant financial interest exists upon receipt of income related to such rights and interests of greater than \$5,000.
- 2) The term significant financial interest does **not** include the following types of financial interests:
- i. Salary, royalties, or other remuneration paid by QScint to the Investigator if the Investigator is currently employed or otherwise appointed by QScint, including intellectual property rights assigned to QScint and agreements to share in royalties related to such rights.
 - ii. Any ownership interest in QScint held by the Investigator since QScint is a commercial or for-profit organization and such interest is excluded from the SFI definition per the regulation.
 - iii. 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.
 - iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (US), a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education.
 - v. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (US), a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education.

- 3) Investigators also must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000 (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 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research. The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
 - i. a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a United States Institution of Higher Education.
- 4) Foreign Financial Interests - Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Sponsor : The funding authority for a PHS grant.

4 THE QSCINT FCOI POLICY

This FCOI policy defines the requirements and processes for Investigators or individuals participating in PHS-funded research to identify and properly disclose any FCOIs. It further identifies the responsibilities of the FCOI Manager. In addition, it outlines activities related to management, enforcement, and reconciliation for all appropriate studies, including the role of the Management Committee.

4.1 FCOI TRAINING

All QScint Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to review this FCOI policy and complete the NIH's online FCOI Training module (see section 5, References):

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years

- Immediately if:
 - QScint revises its FCOI policy that affects requirements of Investigators
 - An Investigator is new to QScint
 - An Investigator is not in compliance with the policy or management plan

Upon completion of the training, a certificate of completion must be sent to the FCOI Manager. The Investigator(s) shall also retain a copy for their records.

4.2 DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS

4.2.1 Disclosure

The Principal Investigator of a Research Project will identify all Investigators required to disclose SFIs (and those of the Investigator's spouse, partner, and dependent children) related to PHS funded activity, which meet the definition of SFI. The Principal Investigator and FCOI Manager will be responsible for ensuring disclosures of any new (e.g., marriage, purchase, or inheritance) or increased financial interests are completed:

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

4.2.2 Review

The FCOI Manager has the following responsibilities **prior** to the expenditure of PHS funds:

- The FCOI Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists related to an Investigator's institutional responsibilities.

An Investigator's SFI is related to the research when the designated official reasonably determines the SFI:

- could be affected by the PHS/NIH-funded research;
- or is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

The designated official may involve the Investigator in determining whether an SFI is related to the research supported by the award.

A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH funded research. ("Significantly" means that the financial interest would have a material effect on the research).

4.2.3 Management

In the case that it is determined by the FCOI Manager that there is a potential conflict of interest, then the FCOI Manager will be responsible for the following:

- Determining and documenting what steps are needed to manage, reduce, or eliminate specific SFI to prevent the potential to compromise or bias professional judgement or objectivity regarding the design, conduct, or reporting of research.
- Recommend the above identified steps to the Management Committee for introducing a FCOI management plan or updating any existing FCOI management plan for the given project

based on the recommendations with the aim of improving controls to ensure compliance with this FCOI Policy.

- Implementing any management plan delegated to the FCOI Manager by the Management Committee.

For any FCOI management plan introduced, all Investigators must formally agree to the proposed management strategies, and all management plans must be signed by the Investigator(s).

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Financial Conflict of Interest. The FCOI Manager shall submit the FCOI report to NIH via the eRA Commons FCOI Module.

4.2.4 Monitoring

The FCOI Manager shall be responsible for monitoring compliance with the management plan over the lifetime of the project.

4.3 REPORTING REQUIREMENTS

The FCOI Manager shall be responsible for reporting on any matters involving disclosures of SFI in accordance with the applicable federal requirements.

The following reports are required:

- **Initial Report:** Prior to the QScint's expenditure of any funds under a PHS/NIH-funded research project, QScint will provide to the Sponsor an FCOI report regarding any Investigator SFI, if found by QScint to be a financial conflict of interest, in accordance with the regulation. In cases in which QScint identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, QScint shall not submit an FCOI report to the NIH.
- **During on-going PHS/NIH-funded research projects:** If during a Research Project, a new Investigator discloses SFI or an existing Investigator discloses a new SFI, QScint shall:
 - Review the disclosure of SFI
 - Determine whether it is related to research
 - Direct the FCOI Manager to implement a FCOI management plan in interim
 - Submit a report of FCOI within 60 days after its determination that a new FCOI exists.
- **Annual Report:** For any FCOI previously reported to the Sponsor, QScint shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. Further, GSK will notify the Sponsor promptly:
 - If bias is found, QScint will notify and submit a mitigation report to the Sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed above) and a description of the impact of the bias on the research project and QScint's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, QScint shall submit FCOI reports annually.
 - If an Investigator fails to comply with QScint's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded

research QScint shall take corrective action by direction of the Management Committee.

4.4 MAINTENANCE OF RECORDS

The Management Committee or their designee shall be responsible for maintaining records of any Investigator SFI disclosure forms, as well as any actions taken to manage actual or potential financial conflicts of interest. The Management Committee shall be responsible retaining said records for at least three (3) years from the date that the final expenditure report is submitted to the Sponsor or - where applicable - from other dates specified in 45 CFR 75.361 for different situations.

4.5 ENFORCEMENT MECHANISMS, REMEDIES, AND NONCOMPLIANCE

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, disciplinary proceedings may be taken against the violating individual.

Complying with this FCOI Policy and any management plan are conditions for employment at QScint.

When an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a FCOI, failure by the Institution to review or manage such an FCOI; and failure by the Investigator to comply with a management plan, QScint will within 120 days:

- Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
- Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B)

QScint shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, the Management Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of QScint's independent retrospective review. If bias is not found, no further action is required.

In any case in which the Sponsor determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a vaccine, drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by QScint as required by this subpart, QScint shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the PHS-funded research and to request an addendum to previously-published presentations under PHS-funded research.

4.6 PUBLIC ACCESSIBILITY OF THIS POLICY AND FCOI AVAILABILITY

QScint shall publish this policy in its most up-to-date version on its public website (www.qscint.com).

QScint shall respond to all written requests for information on SFI within five (5) calendar days and then release the required information about such SFI containing, at a minimum the following:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the Significant Financial Interest is held;
- The nature of the Significant Financial Interest;
- The approximate dollar value of the Significant Financial Interest in the following ranges: \$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.

5 REFERENCES

- United States Code of Federal Regulations 42 CFR Part 50 Subpart F (e.g. <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50>)
- NIH FCOI Training Module (presently accessible in its most up-to-date form at the appropriate link at this site: <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>)

6 REVISION HISTORY

[Refer to Document Management System for Revision History]