

National Quality Forum (NQF)

National Institute of Health (NIH) Project(s) Financial Conflict of Interest

Standard Operating Procedures

I. Purpose

To identify and mitigate conflict(s) of interest related to NQF projects funded by NIH.

II. Definitions

Financial Conflict of Interest (FCOI) – a SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Investigator(s) – the project director or principal investigator and any other person, regardless of title or position, who is responsible for design, conduct, or reporting of research funded by the Public Health Service of the U.S. Department of Health and Human Services (PHS), including the National Institutes of Health (NIH), or proposed for such funding, which may include, for example, collaborators or consultants.

PD/PI – a project director or principal investigator for the NIH project.

PHS – 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).

Senior/Key Personnel – the PD/PI and any other person identified as senior/key personnel by NQF in the grant application, progress report, or any other report submitted to NIH.

Significant Financial Interest(s) (SFI) –

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

- 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), upon receipt of income related to such rights and 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 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.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or 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.

III. Internal Disclosure, Review, and Monitoring

A. Prior to Application

Prior to the application for an NIH research project the PD/PI shall:

1. Identify all Investigators that may work on the NIH project;
2. Provide a copy of this standard operating procedures document to each Investigator;
3. Require all Investigators to complete **Attachment A Disclosure Statement** (and annually thereafter during the period of the contract award);
4. Review, in coordination with the Enterprise Corporate Compliance and Privacy Officer, all Investigators Disclosure Statement(s) and determine if:
 - an Investigators SFI relates to PHS-funded research; and
 - an FCOI exist.

5. If it has been determined that a FCOI exists, coordinate with the Enterprise Corporate Compliance and Privacy Officer on the development of plans to manage the identified conflict (see 42 CFR 50.605(a) for plan development).

B. New Investigator(s)

For any Investigators that are added to an NIH research project, and prior to the new Investigators participation in such projects, the PD/PI shall:

1. Provide a copy of this standard operating procedures document to each new Investigator;
2. Require all new Investigators to complete **Attachment A Disclosure Statement** (and annually thereafter during the period of the contract award);
3. Review, in coordination with the Enterprise Corporate Compliance and Privacy Officer, all new Investigators Disclosure Statement(s) and determine if:
 - an Investigators SFI relates to PHS-funded research; and
 - a FCOI exist.
4. If it has been determined that a FCOI exists, coordinate with the Enterprise Corporate Compliance and Privacy Officer on the development of plans to manage the identified conflict (see 42 CFR 50.605(a) for plan development).

C. Undisclosed SFI(s)

If the PD/PI becomes aware of any SFI that was not disclosed in a timely manner or an SFI that was not previously reviewed, within sixty (60) days of discovery, the PD/PI shall:

1. Review, in coordination with the Enterprise Corporate Compliance and Privacy Officer, and determine if:
 - the SFI relates to PHS-funded research; and
 - a FCOI exist.
2. If it has been determined that a FCOI exists, coordinate with the Enterprise Corporate Compliance and Privacy Officer on the development of plans to manage the identified conflict (see 42 CFR 50.605(a) for plan development).
3. Follow the Noncompliance section below.

IV. Training

Prior to an Investigator participating in an NIH research project, the PD/PI shall provide training to each Investigator on this standard operating procedures document and the Investigator(s) responsibilities. Follow up training must be provided by the PD/PI to each Investigator at least every four (4) years during the period of contract award. The PD/PI will be responsible to document completion of the training consistent with this standard operation procedures document. Additional training will be immediately provided if (1) changes are made to this standard operating procedures document that affect requirements of an Investigator; (2) an investigator is new to the project; or (3) an Investigator is found to be noncompliant with this document or the FCOI management plans.

V. Reporting to NIH

A. FCOI Reports

The PD/PI shall send, initial, annual (i.e., ongoing) and revised FCOI reports to NIH:

1. Prior to the expenditure of funds;
2. Within sixty (60) days of identification for an Investigator who is newly participating in the project;
3. Within sixty (60) days for new, or newly identified, FCOIs for existing investigators;
4. At least annually (at the same time as when NQF is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, until completion of the project; and
5. Following a retrospective review to update a previously submitted report, if appropriate (reporting will be done consistent with 42 CFR 50.605(a)(3)(iii)).

The FCOI report shall include sufficient information to enable NIH to understand the nature and extent of the financial conflict, and to assess the appropriateness of NQF's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- 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 PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- 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.

B. Bias Reporting:

If a Bias is found with the design, conduct, or reporting of NIH-funded research project, the PD/PI will submit to NIH a mitigation report.

The mitigation report must include, at a minimum:

(1) Key elements for a retrospective review, including:

- 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 financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

(2) description of the impact of the bias on the research project; and

(3) NQF'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).

The PD/PI shall provide notification to NIH if an Investigator fails to comply with this standard operation procedures document or any applicable FCOI management plans and it appears that it will bias the design, conduct, or reporting of the NIH-funded project.

VI. Maintenance of Records

The PD/PI shall ensure that all FCOI records are stored and maintained for at least three (3) years from the date the final expenditure report is submitted to NIH (including all reports, disclosure statements, etc.). All records will be maintained in accordance with NQF and/or Enterprise document retention policies.

VII. Enforcement Mechanisms

If a compliance issue is identified, the PD/PI will be notified in writing and take action in the following order successively until resolved:

1. Engage with corporate governance to provide counseling and appropriate training to the individual to improve understanding of COI SOPs and requirements
2. Identify compliance issue to individual's supervisor for performance resolution

3. Engage human resources to develop an individual performance improvement plan to remedy COI
4. Remove individual from project

VIII. Noncompliance

The PD/PI shall complete and document retrospective reviews within 120 days of NQF's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner (see 42 CFR 50.605(a)(3)). The documentation of the retrospective review shall include the following:

- 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 financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

In cases in which the Department of Health and Human Services determines that the NIH project was not managed or reported by NQF as required by the regulation, NQF shall require the Investigator to:

1. Disclose the FCOI in each public presentation of the results of the research; and
2. Request an addendum to previously published presentations.

IX. Subrecipient

If NQF utilizes subrecipient for work on NIH research projects (e.g., subcontractors or consortium members), and as applicable, NQF will ensure that any such subrecipient:

1. Provides NQF with a certification that the subrecipient's FCOI policy complies with 42 CFR 50.604.
2. Has a written contract or agreement with NQF that requires the subrecipient to immediately report identified FCOIs for its investigators, but at a minimum in a time frame that allows the awardee institution sufficient opportunity to report identified FCOIs to NIH as required by regulation. Alternatively, the written contract or agreement between subrecipient and NQF will allow NQF the ability immediately solicit and review the subrecipient Investigator(s) disclosures, but at a minimum in a time frame that allows the awardee institution sufficient opportunity to identify, manage, and report identified FCOIs to NIH as soon as possible.
3. Prior to the expenditure of funds, and within sixty (60) days of any subsequent identified FCOI, provide an FCOI reports to NIH regarding all financial conflicts of interest of all subrecipient Investigators consistent with 42 CFR 50.604.

X. Public Accessibility

The PD/PI shall ensure that this standard operation procedures document is publicly accessible by posting it on NQF's public website.

All information concerning identified FCOIs for Senior/Key Personnel shall be provided to any requestor withing five (5) calendar days of a written request. The information shall include the following:

1. The Investigators name, title and role with respect to the research project;
2. The name of the entity in which the significant financial interest is held;
3. The nature of the significant financial interest; and
4. The approximate dollar value of the significant financial interest (dollar ranges are permissible: (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.

***All information must remain available for three (3) years from the date the information was most recently updated.**

**National Quality Forum (NQF)
National Institute of Health Project(s)
Financial Conflict of Interest Disclosure**

This is the detailed Financial Conflict of Interest Disclosure Form which designated individuals are asked to complete and return. Please refer to the National Institute of Health Projects Financial Conflict of Interest SOP for questions or call the Compliance and Privacy Officer at 630-792-5627 or the Compliance and Privacy Manager at 630-792-5037 to discuss any conflicts. Tip: If you are not sure, it is always good to overreport so that the PD/PI and Compliance can review any potential conflicts.

Answer the following disclosure questions to the best of your knowledge on behalf of yourself and your family (spouse and dependent children) as of the date of completing this form and relative to the most recent twelve months preceding completion of the disclosure.

Significant Financial Interests (SFI) (see definition in the SOP document)

To the best of your knowledge:

1. Do you (or your spouse or dependent children) have a significant financial interest that reasonably appears to be related to NQF’s institutional responsibilities:
 - 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 you (or your 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 rights and interests.

Yes No

If yes, please identify _____

2. Have you been reimbursed or sponsored travel (*i.e.*, that which is paid on your behalf and not reimbursed to you so that the exact monetary value may not be readily available), related to your NQF 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.

Yes No

If yes, 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:

I read, understand, and agree comply with the National Institute of Health Project(s) Financial Conflict of Interest Standard Operating Procedures. I also understand that I must provide immediate updates to the PD/PI or Compliance if I become aware of any new or previously undisclosed SFIs.

Name

Date