

POLICY ON FINANCIAL CONFLICTS OF INTEREST (FCOI) IN PUBLIC HEALTH SERVICE (PHS) FUNDED RESEARCH

I. Purpose and Scope of Policy

This Policy implements FCOI disclosure requirements found in 42 CFR Part 50 (grants and cooperative agreements) and 45 CFR Part 94 (contracts) which are applicable to Research funded by the U.S. Public Health Service. As a condition for receiving PHS funding, these regulations require Battelle to maintain an appropriate written policy on financial conflict of interest disclosure. These requirements are applicable to all Research projects for which Battelle submits a proposal to or receives Research funding from PHS. Each Investigator who is planning to participate in, or is participating in such Research, must follow this process. Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy.

The PHS FCOI Regulations and this Policy are intended to ensure objectivity in which Research projects are designed, conducted or reported by managing FCOI that occur between an Investigator's personal financial interests and his/her professional Research interests. It establishes a process of disclosure and independent review when an Investigator has a Significant Financial Interest (SFI). If Battelle determines that such an interest might reasonably appear to affect the Research directly and significantly, Battelle will develop a mitigation plan to manage or eliminate the conflict.

This Policy is available at the following public accessible website: <http://www.battelle.org/site/disclosure-statement> under the Disclosures heading.

II. Definitions

A. *Financial Conflict of Interest (FCOI)*

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

B. *Investigator*

An Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator (PI), Co-Investigators, consultants, subcontractors, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this Research.

C. *Institutional Official (IO)*

An official designated by Battelle to solicit and review completed Disclosure Forms from each Investigator who is planning to participate in, or who is participating in, PHS funded Research and to determine whether any reported SFI is a FCOI. References to the IO in this document include his/her delegate.

D. *Institutional Responsibilities*

Institutional Responsibilities means an Investigator's professional responsibilities performed on behalf of Battelle.

E. PHS Awarding Component

PHS Awarding Component means the organizational unit of the PHS that funds the Research.

F. Research

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research as well as product development (e.g., a diagnostic test or drug).

G. Senior/Key Staff

Senior/Key staff means the PI and any other person identified as Senior/Key staff by Battelle in the grant application, proposal or any other report submitted to the PHS Awarding Component.

H. Significant Financial Interest (SFI)

Significant Financial Interest means either of the following:

- (1) Any interest of the Investigator, his/her spouse, and dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities, including, but not limited to, one or more of the following:
 - a. With regard to any publicly traded entity, a SFI 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) and 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;
 - b. With regard to any non-publicly traded entity, a 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); or
 - c. 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.

Note: The term SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by Battelle to the Investigator if the Investigator is currently employed or otherwise appointed by Battelle, including intellectual property rights assigned to Battelle and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, provided 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. Disclosure Requirement

Each Investigator who is planning to participate in PHS funded Research is required to disclose to Battelle his/her SFIs, his/her spouse's SFIs and his/her dependent children's SFIs no later than the time of application for PHS funded Research. Each Investigator must do so by completing the Disclosure Form available at the following website: <http://www.battelle.org/site/disclosure-statement> under the **Disclosures** heading. This disclosure obligation is created initially by the Investigator's intent to participate in PHS funded Research.

When PHS funded Research opportunities arise, Battelle Contracting Officers send by email a reminder to the applicable staff of these obligations. Prior to submission of a proposal or application for PHS funded Research, Battelle Contracting Officers shall review all required Disclosure Forms and notify the IO of any SFIs reported on the Disclosure Forms.

Additionally, each Investigator, which includes staff responsible for the design, conduct, or reporting of Research funded by the PHS, is required to submit an updated Disclosure Form to the Battelle IO at INSTITUTEOFFICIAL@battelle.org either within 30 days of discovering or acquiring a new SFI, or at least on an annual basis in October of each year. If an Investigator does not have any SFIs to report, the Investigator must still complete the Disclosure Form annually. Battelle Project Managers shall ensure applicable staff comply with these disclosure obligations. Failure to comply with these disclosure obligations may result in disciplinary action.

IV. Review of Disclosures and Management of FCOIs

A. Review Requirement

Prior to Battelle's expenditure of any funds under a PHS funded Research project, the Battelle IO will review all Disclosure Forms with SFIs to determine whether the SFIs relate to the PHS funded Research and whether a FCOI exists. If a FCOI exists, the Battelle IO will develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

B. Disclosure/Identification of SFI

- (1) Whenever, in the course of an ongoing PHS funded Research project, (1) an Investigator who is new to participating in the Research project discloses a SFI; (2) an existing Investigator discloses a new SFI; or (3) Battelle identifies a SFI that was not disclosed timely by an Investigator or was not previously reviewed by Battelle during an ongoing PHS funded Research project, the Battelle IO within sixty days of the disclosure will review the SFI to determine whether it is related to PHS funded Research and whether a FCOI exists. If a FCOI exists, the Battelle IO will develop and implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, Battelle may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded Research project between the date of disclosure and the completion of Battelle's review.
- (2) Prior to Battelle's expenditure of any funds under a PHS funded Research project, Battelle must post to its public accessible website, <http://www.battelle.org/site/disclosure-statement> under the Disclosures heading, information concerning any SFI disclosed to Battelle that is (a) held by Senior/Key Staff performing services for the project, (b) related to the PHS funded research, and (c) determined by Battelle to be a FCOI. The following information regarding

the FCOI must be posted to the website:

- Project number;
- Name of the Investigator with the FCOI, title, and role with respect to the Research project;
- Name of the entity with which the Investigator has an 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 readily be determined through reference to public prices or other reasonable measures of fair market value;

This information must be updated at least annually as well as within 60 days of the following events:

- a. Battelle's receipt or identification of information concerning any additional SFI of the Senior/Key Staff for the PHS funded Research project that was not previously disclosed; or
- b. upon disclosure of any SFI of Senior/Key Staff new to the PHS funded Research project and meeting the disclosure criteria.

The website shall note that the information is current as of the date shown and is subject to the required updates. Any SFI posted to the website shall remain available for at least three years from the date that the information was most recently updated by Battelle.

C. *Management of FCOI*

Examples of conditions or restrictions that may be imposed to manage an FCOI include, but are not limited to the follow actions:

- Public disclosure of the FCOI (e.g. when presenting or publishing research);
- For Research projects involving human subjects, disclosure of the FCOI 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 FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the financial interest; or
- Severance of relationships that create financial conflicts.

D. *Retrospective Reviews*

Whenever a FCOI is not identified, disclosed or managed in a timely manner or an Investigator fails to comply with a FCOI management plan, Battelle has additional review and reporting obligations. If in these situations Battelle determines that a SFI constitutes a FCOI, Battelle's IO will, within 120 days of Battelle's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded Research project to determine whether any PHS funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. Battelle is required to document the retrospective review. Documentation shall include all of the following key elements: (1) Project number; (2) Project title; (3) PI or contact PI if a multiple PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has an FCOI; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

As necessary, based on the results of the retrospective review, Battelle will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Battelle will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Minimally, the mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the Research project, and Battelle'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, Battelle will submit FCOI reports annually. Depending on the nature of the FCOI, Battelle may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of Battelle's retrospective review.

E. Monitoring

Whenever Battelle implements a management plan, Battelle will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

V. Reporting of Financial Conflicts of Interest

A. Initial FCOI Report

Prior to Battelle's expenditure of any funds under a PHS funded Research project, Battelle will provide to the PHS Awarding Component a FCOI report regarding any Investigator's SFI found by Battelle to be a FCOI. Additionally, Battelle will ensure that it has implemented a management plan in accordance with Section IV of this Policy. In situations in which Battelle identifies an FCOI and eliminates it prior to the expenditure of PHS awarded funds, Battelle is not required to submit an FCOI report to the PHS Awarding Component.

B. Subsequent FCOI Reports

For any SFI that Battelle identifies as a FCOI after Battelle's initial report during an ongoing PHS funded Research project, Battelle will provide to the PHS Awarding Component a FCOI report regarding the FCOI within 60 days of identification of the FCOI. Additionally, Battelle will ensure that it has implemented a management plan in accordance with Section IV of this Policy and, if required, complete a retrospective review and a mitigation report according to Section IV of this Policy.

C. Contents of a FCOI Report

Any FCOI report required under paragraphs A or B of this Section V will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of Battelle's management plan. The FCOI report will include the following minimum information:

- (1) Project number;
- (2) PI or Contact PI if a multiple PI model is used;
- (3) Name of the Investigator with the FCOI;
- (4) Name of the entity with which the Investigator has an FCOI;
- (5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (6) 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 readily be determined through reference to public prices or other reasonable measures of fair market value;

- (7) A description of how the financial interest relates to the PHS funded Research and the basis for Battelle's determination that the financial interest conflicts with such Research; and
- (8) A description of the key elements of Battelle's management plan including the following minimum information:
 - a. Role and principal duties of the conflicted Investigator in the Research project;
 - b. Conditions of the management plan;
 - c. Explanation of how the management plan is designed to safeguard objectivity in the Research project;
 - d. Confirmation of the Investigator's agreement to the management plan; and
 - e. Explanation of how the management plan will be monitored to ensure Investigator compliance.

D. Annual FCOI Report

For any FCOI previously reported by Battelle regarding an ongoing PHS funded Research project, Battelle will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Battelle will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

VI. Enforcement

If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Battelle is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Battelle. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Battelle for further action, which may include directions to Battelle on how to maintain appropriate objectivity in the PHS funded Research project. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of SFI related to federally sponsored projects.

Failure by Battelle staff to comply with this Policy may be grounds for disciplinary action up to and including termination.

VII. Record Retention

Records regarding Disclosure Forms, determinations made by Battelle's IO, and Battelle's actions regarding management of an FCOI will be retained by Battelle for three years beyond the date of the final expenditure report submitted to the PHS Awarding Component under an award or, where applicable, from other dates specified in 45 CFR 74.53(b) and 45 CFR 92.42(b)..

VIII. Training

Each Investigator must complete training prior to engaging in PHS funded research. Additionally, Investigators must complete training at least every four years and must immediately complete training under the following circumstances:

- Battelle's FCOI policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Battelle; or

- Battelle determines that an Investigator is not in compliance with Battelle's FCOI policy or management plan.

IX. Subcontractors/Consultants

Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy. All applicable subcontract/consulting agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy. Examples of appropriate clauses are shown below.

Financial Conflicts of interest – Compliance with Subcontractor's Policy

Subcontractor agrees to comply with any and all requirements relating to Public Health Service (PHS) funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor certifies that it maintains a policy that requires compliance with these requirements. Subcontractor shall report all identified financial conflicts of interests to Battelle immediately and submit a mitigation plan for Battelle's review and approval. Battelle is under no obligation to approve a mitigation plan. Battelle reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.

Financial Conflicts of interest – Compliance with Battelle's Policy

Subcontractor agrees to comply with any and all requirements relating to Public Health Service (PHS) funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor agrees to comply with Battelle's Policy on Financial Conflicts of Interest in Public Health Service (PHS). Subcontractor shall report all identified financial conflicts of interests to Battelle immediately and submit a mitigation plan for Battelle's review and approval. Battelle is under no obligation to approve a mitigation plan. Battelle reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.