

FREQUENTLY ASKED QUESTIONS REGARDING BATTELLE'S POLICY ON FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE (PHS) FUNDED RESEARCH

The Financial Conflict of Interest (FCOI) regulations apply to Institutions that apply for or receive Public Health Service (PHS) research funding through a grant, cooperative agreement, or contract. PHS means the Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS. PHS Awarding Component means the organizational unit of the PHS that funds the 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract whether authorized under the PHS Act or other statutory authority.

Who is covered by the regulation, who must complete a Disclosure Form, and where do I send the Disclosure Form?

The regulation is applicable to Battelle when it is applying for, or receives, PHS research funding through a grant, cooperative agreement, or contract. It also applies to each Investigator who is planning to participate in, or is participating in, such research. For financial disclosure purposes only, the regulation covers the Investigator's spouse and dependent children. All staff meeting the definition of an Investigator, as defined below, must complete a Disclosure Form. The Disclosure Form template may be found at <http://www.battelle.org/site/privacy-statement-and-disclosures> under the Disclosures heading. The initial annual Disclosure Form should be sent to Battelle's IO at INSTITUTEOFFICIAL@battelle.org. For specific proposals or projects, the Disclosure Form should be submitted in accordance with the Contracting Officer's instructions.

Who is considered an "Investigator" for the purpose of this regulation? Is it only the Principal Investigator?

No. "Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, subcontractors or consultants. It is the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

What is a "Financial Conflict of Interest" (FCOI)?

A FCOI exists when Battelle, through its Institutional Official (IO), reasonably determines that an Investigator's Significant Financial Interest (SFI) is related to a PHS funded research project and could directly and significantly affect the design, conduct or reporting of the PHS funded research.

The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

A “Significant Financial Interest” (SFI) is defined as follows:

- (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 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;
 - ii. 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
 - 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. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
 - 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.Battelle’s FCOI policy requires the following minimum details to be included in the disclosure:
 - purpose of the trip,
 - the identity of the sponsor/organizer
 - the destination, and
 - the duration.
- (3) 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;
 - 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, 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 in 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;

- income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

What are “institutional responsibilities”?

“Institutional responsibilities” are defined as an Investigator’s professional responsibilities performed on behalf of Battelle.

Am I required to disclose interests in mutual funds or retirement accounts?

Maybe. The disclosure of income from investment vehicles, such as mutual funds and retirement accounts, is not required provided that the Investigator does not directly control the investment decisions made in these vehicles.

When should I disclose my financial interests to Battelle?

SFIs must be disclosed to Battelle’s IO:

- prior to the submission of an application or proposal to a PHS Awarding Component;
- within thirty (30) days of discovering or acquiring a new SFI; and
- annually each October.

What about financial interests acquired or discovered during the award period subsequent to the submission of the initial report?

Investigators have an ongoing obligation to disclose SFIs throughout the awarded project period. Investigators must update financial disclosures of SFIs to Battelle within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new SFI by sending an updated Disclosure Form to Battelle’s IO at INSTITUTEOFFICIAL@battelle.org. Battelle’s IO will have sixty (60) days to review the SFI disclosure, determine whether the SFI is related to PHS funded research, determine whether a FCOI exists, and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI. If a FCOI exists, Battelle must submit a FCOI report to the PHS Awarding Component within this same 60-day period.

Does the regulation require Investigator training?

Yes. Requirements and access to training may be found at <http://www.battelle.org/site/privacy-statement-and-disclosures> under the [Disclosures](#) heading. Each Investigator must complete training prior to engaging in PHS funded research, at least every four years, and immediately under the following circumstances:

- Battelle’s FCOI policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Battelle;
- Battelle determines that an Investigator is not in compliance with Battelle’s FCOI policy or management plan.

Does the regulation apply to subcontractors or 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.