

Financial Conflict of Interest (FCOI) Policy for ASHA's PHS-Funded Activities and Programs

All key personnel involved with ASHA's grants supported by Public Health Service (PHS) funding are required to complete a disclosure form indicating any financial relationship related to the content or aims of the grant.

[Financial conflict of interest \(FCOI\) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.](#) Completion of the disclosure form is necessary to promote transparency in the design, development, implementation, and dissemination of the grant plan, and to comply with federal regulation.

ASHA defines a financial conflict of interest as any financial interest, consideration, or relationship that has the potential to compromise, bias, or impede one from maintaining research integrity. All key personnel on ASHA's PHS-funded activities and programs must identify and disclose any such financial conflicts of interest.

Guidelines: Disclosable Financial Conflicts of Interest

- Being an employee of, or a paid consultant to, an organization whose products or services you discuss in your presentation
- Receiving royalties from the sale of a book whose content you discuss in your presentation
- Patent holder for a product you discuss in your presentation
- Ownership interest (stocks, stock options, or other ownership interests) in a product you discuss in your presentation
- PHS-funded research does not constitute an FCOI for ASHA's PHS-funded activities and programs

Training

The Principal Investigator/Program Director (PI/PD) of any ASHA PHS-funded ASHA activity or program will complete FCOI training at least every four years.

Review and Monitoring Requirements

Key personnel are required to disclose significant financial interests (SFIs) (and those of their spouse and dependent children) related to their roles and responsibilities with ASHA's PHS-funded activities and programs that meet or exceed the regulatory definition of SFI. Designated institutional officials, including the PI/PD, will solicit and review disclosures of SFIs:

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

Review Process

The PI/PD will:

- Review all key personnel SFI disclosures
- Determine if any SFIs relate to ASHA's PHS-funded activities and programs

- Determine if a FCOI exists relative to ASHA's PHS-funded activities and programs
- Implement the Management Plan if a FCOI is identified

Reporting Requirements to NIH

Any FCOIs will be reported to NIH at the time of submitting the annual progress report and as otherwise required by the regulation. ASHA will notify NIH and take corrective action for noncompliance with ASHA's PHS-funded FCOI policy or the Management Plan.

Maintenance of Records

ASHA collects FCOI-related records through an online system and maintains them for at least 3 years from the date the final expenditures report is submitted to the PHS.

Enforcement Mechanisms and Remedies and Noncompliance

The Management Plan consists of the key personnel disclosing their identified FCOIs at the time of ASHA's PHS-funded activities and programs. If the FCOIs are deemed to be potentially detrimental to ASHA's goals, the key personnel will be relieved of their duty in the PHS-funded ASHA activity or program. If a FCOI is identified after the ASHA PHS-funded activity or program takes place, ASHA shall require the key personnel to provide an addendum to that publication or recorded presentation.

Public Accessibility Requirements

The FCOI Policy for ASHA's PHS-Funded Activities and Programs is accessible via www.asha.org/siteassets/uploadedfiles/fcoi-policy.pdf. If FCOIs held by senior key personnel are identified, this information will be made publicly available on the ASHA website and updated annually. This will include minimum elements as provided in the regulation and remain available for three years from the most recent update.

For more information regarding relevant regulations, see [42 CFR Part 50 Subpart F](#).