

QuSpin Inc. Protocol for Handling Financial Conflict of Interest

This protocol along with the policy and procedure titled, Financial Conflict of Interest in PHS-Funded Projects, constitute the QuSpin FCOI policy. Capital terms in this protocol shall have the same meaning as set forth in the policy. This protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607).

This document specifies the FCOI protocol for PHS-funded research: that is the step-by-step implementation of the QuSpin FCOI policy.

1. Who is required to disclose financial interests

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests (“PHS-funded Investigators”).

2. SFI disclosure

PHS-funded Investigators are required to disclose SFIs to either a member of the QuSpin MT or the designated QuSpin FCOI official, as follows:

1. Employees planning to participate in PHS-funded research are required to disclose all SFI's prior to submission of an application for PHS-funded research.
2. Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI,
 - o When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
3. All PHS-funded investigators shall submit an updated SFI disclosure annually.
4. SFI disclosures (except travel) must include the following information:
 1. Identity of the sponsor/organizer; and
 2. Nature of SFI (e.g., salary, license income, stock).
5. Externally funded travel also constitutes SFI, and therefore the disclosure requirements in 2 (i)-(iii) apply. That is, PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - o Purpose,
 - o Identity of the sponsor/organizer,
 - o Destination, and,
 - o Duration.

3. Review of disclosures

All SFI disclosures, including those submitted by a new investigator who joins an ongoing PHS-funded project, will be reviewed by the designated QuSpin FCOI official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated QuSpin FCOI official may involve the relevant investigator in the review, and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated QuSpin FCOI official will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the designated QuSpin FCOI official will conduct a retrospective review of SFIs for the PHS-funded investigator within one hundred twenty (120) days and document it.

4. Management of FCOI

For each disclosure that leads to determination of FCOI, the QuSpin MT will discuss and approve the implementation of a management plan developed by the designated QuSpin FCOI official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

1. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
2. Conditions of the management plan (see examples below);
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
5. How the management plan will be monitored to ensure PHS-funded Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- For research projects involving human subjects research, disclosure of financial conflicts of interest 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 Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

QuSpin Inc.

331 South 104th Street, Suite 130
Louisville, CO 80027

Email: info@quspin.com

Tel: +1-303-325-7733