

The Public Health Service has announced new and revised regulations governing financial conflicts of interest for its researchers and their families. Agencies included in the Public Health Service (PHS) are:

- [Agency for Healthcare Research and Quality](#) (AHRQ)
- [Agency for Toxic Substances and Disease Registry](#) (ATSDR)
- [Centers for Disease Control and Prevention](#) (CDC)
- [Food and Drug Administration](#) (FDA)
- [Health Resources and Services Administration](#) (HRSA)
- [Indian Health Service](#) (IHS)
- [National Institutes of Health](#) (NIH)
- [Substance Abuse and Mental Health Services Administration](#) (SAMHSA)

The full regulations can be found here: [42 CFR Part 50, subpart F](#) and [45 CFR Part 94](#).

In brief, the regulations detail new amounts that constitute a significant financial interest, require the reporting of travel reimbursements and intellectual property, and training requirements for researchers.

Specifically:

Who does it cover? It covers applicants and recipients of PHS funds used for research and members of their immediate households (spouse/partner and dependent children.) A researcher under these regulations ***includes anyone with independent responsibility for a part of the research*** and can include but is not limited to the PI, co-PIs, senior/key personnel, post-docs, consultants and subcontractors or sub-awardees. Applicants and recipients of SBIR and STTR funds are exempt from this reporting requirement.

What is a significant financial interest? A significant financial interest is any amount (\$5,000 or more) including salaries or payments outside of an individual's regular salary from the university. This can include honoraria, speaker fees etc. Additionally, it includes equity interests in publically traded companies, equity interests in private or non-publically traded companies, intellectual property rights or patents and any reimbursed or sponsored travel related to their institutional responsibilities.

What is not included in a significant financial interest? Income from seminars, lectures, or teaching engagements sponsored by and service on advisory 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. Additionally, income from investment vehicles, such as mutual funds and retirement

accounts, are excluded as long as the Investigator does not directly control the investment decisions made in these vehicles.

When do I report it? Significant financial interests must be reported at the time of application, at the initial award and each year of the award, and whenever a change brings a financial interest to the significant level.

How do I report it? To report Significant Financial Interests, you submit the SFI form found in the [forms section](#) of the OSP website. A properly completed form will contain the necessary information that the Associate Provost for Research or the designee needs to determine if the significant financial interest constitutes a financial conflict of interest or FCOI.

What if I have an FCOI? What happens? If it is determined by the Associate Provost for Research or the designee that you may have an FCOI, a management committee (the Associate Provost for Research, the Office of General Counsel, the Dean and the Chair of the applicant) would meet to decide the appropriate means of managing the FCOI. If the FCOI is then eliminated, nothing will be reported to the PHS. If it is not able to be eliminated, then the PHS will be notified. Additionally, upon request, the University must make the management plan available to the public within 5 working days.

What happens if I don't manage my FCOI according to the plan or don't report all of my SFI? If you do not comply with the management plan or reporting requirements, the University is responsible for initiating an investigation. Additionally, the University must notify the PHS and the agency could initiate its own investigation.

Is there any training involved? Yes, there is training involved. Through our relationship with CITI Programs, we have begun to offer a "Conflict of Interest" course that covers the PHS regulations. All individuals that are required to submit an SFI form must take the training every 4 years or whenever changes are made to the regulations.

How long are the SFI forms kept? The forms must be kept for 3 years after the submission of the final spending report. The forms will be kept and managed by the Office of Sponsored Programs and/or the Office of Research.