



Department-level Public Health Service (PHS) COI Review of Consulting Agreements

For Significant Financial Interests (SFIs) valued between \$5,001-\$10,000

Overview

The [Public Health Service \(PHS\) COI regulations](#) require that the University determine if any Significant Financial Interest (SFI)ⁱ disclosed by an investigatorⁱⁱ on a PHS-funded projectⁱⁱⁱ gives rise to a Financial Conflict of Interest (FCOI)^{iv} with the research.

For SFIs in **public companies (aggregated value of remuneration and equity holdings)** that **exceed \$5,000, but not \$10,000** in value in a 12-month period and **remuneration from privately held companies** that **exceeds \$5,000, but not \$10,000** in a 12-month period, this responsibility lies with the department.

Supervisor Determination

Supervisors should consider the following questions to determine if the proposed remuneration from the company is related to any of PHS-funded projects on which the individual serves as an investigator (these should all be listed under question 8 of his/her PHS Faculty/Researcher COI disclosure form^v).

1. Is the work being done under any of these PHS grants or contracts ***evaluating or further developing any of the company's products or intellectual property?***
2. To your knowledge, are any of these PHS-funded research projects ***evaluating or further developing any product of a competitor of the company?***
3. Is the **company providing funding or other support** (e.g., drugs or devices) for any of these PHS-funded projects?

If the answer to any above question is yes, the supervisor needs to determine if the proposed consulting relationship gives rise to an FCOI, that is, whether or not the investigator's SFI could *directly and significantly* affect the design, conduct, or reporting of the PHS-funded project^{vi}, and, if it could, indicate how the FCOI should be managed.

Conflict Management Plans (CMPs)

All management plans must contain the following elements:

- The investigator must disclose his/her financial interest in the company in all abstracts, publications, presentations, and press releases involving research sponsored by the company or that is of commercial interest to the company (e.g., evaluating or further developing its intellectual property).

- The investigator must disclose his/her financial interest in the company in applications or proposals to fund research of commercial interest to the company as directed by the potential funding source. If the instructions are unclear, you will contact the agency or sponsor for guidance.
- The individual must provide the COI Office with a list of the personnel engaged in research under this project (students, staff or other faculty members), who will be notified by the COI Office of his/her conflict of interest with this project. The investigator must inform the COI Office when new personnel are added to the project.
- Students will be engaged in the project only with the approval of their department chair or dean.
- The investigator must notify the Conflict of Interest Office of any changes in the source(s) of support for this project.

The supervisor may add other elements to the conflict management plan (CMP), such as: the involvement of a data steward or oversight committee; prohibiting the individual from serving as the PI of the study or of any IRB or IACUC protocols funded by the PHS grant or contract; or otherwise limiting the individual's involvement in the research project.

Unmanageable Conflicts

If the supervisor believes the conflict is unmanageable, s/he may require the individual to reduce the value of the financial interest to not exceed \$5,000 in a 12 month period or s/he may not permit the investigator to engage in the outside activity.

Transmittal to COI Office

The result of the department's PHS COI review for a consulting contract should be forwarded to coi@pitt.edu for the COI Office's records.

The COI Office will report managed conflicts of interest to the PHS funding agency. This information will also be posted on the [University's COI website](#).

Assistance

If you need assistance with your review, please feel free to [contact the COI Office](#).

ⁱ **PHS Significant Financial Interest:** See full definition in Section II of [Policy 11-01-03](#).

ⁱⁱ **Investigator:** Any individual who is responsible for or who participates in the design, conduct, or reporting of research.

ⁱⁱⁱ Note that the individual need not be named on the grant funding the project in which s/he participates.

^{iv} **Financial Conflict of Interest (FCOI):** an SFI that could *directly and significantly* affect the design, conduct, or reporting of research.

^v Supervisors can access the PHS Faculty/Researcher forms submitted by individuals in their unit through the administrative database <https://www.hsconnect.pitt.edu/HSC/public/sign-in.htm> or ask the individual to provide a copy of the form with all his/her current PHS projects listed.

Supervisors need do not need to consider research projects funded by non-PHS sources in this review.

^{vi} If the supervisor does not believe the SFI is an FCOI, s/he must document the reason(s) for that determination; for example, by explaining why the role of the investigator in the project is such that s/he cannot *directly and significantly* affect the design, conduct, or reporting of the research. An example could possibly include a multicenter study in which data is analyzed by an independent data center, where the Investigator is not directly or solely involved in the collection, recording, or analysis of the data, etc.