

Department PHS COI Review of Consulting Agreements (SFIs valued between \$5,001-\$10,000)

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 project gives rise to a Financial Conflict of Interest (FCOI)ⁱⁱⁱ 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.

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^{iv}).

1. Is the work being done under any of these PHS grants or contracts **evaluating or developing any of the company's products or intellectual property?**
2. To your knowledge, are any of these PHS-funded research projects **evaluating or 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^v, and, if it could, indicate how the FCOI should be managed. All management plans must contain, at minimum, the following elements:

- The investigator will disclose the existence of his/her SFI in all related abstracts, publications, presentations, and press releases; and in related applications or proposals for research funding only if disclosure is required by the funding source. In cases where disclosure is not required and the investigator wishes to disclose his/her SFI, he/she will contact the funding source for permission and instructions for doing so;
- Other individuals (students, staff, or other faculty members) engaged in the PHS-funded research project with the investigator should be notified of the existence of his/her SFI through the use of the *Notification of Investigator's research-related SFI* form found on the Forms page of the COI website: <http://www.coi.pitt.edu/Forms/Notification.doc>
- Students will be engaged in the project only with the approval of their non-conflicted department chair or dean.

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.

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.

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. **All CMPs must be sent to the COI Office** so the University can report the managed conflict to the PHS funding agency. This information will also be **posted on the University's COI website at <http://www.coi.pitt.edu/PHS/FCOIList.htm>**.

If you need assistance with your review, please feel free to contact the COI Office:

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

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

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

^v 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.