

Guidance for Determining If a Financial Conflict of Interest Is Related to PHS-Funded Sponsored Projects

- (1) The Department Chair or Supervisor and the Office of Research Compliance and Assurance reviews financial conflict of interest disclosures to determine if a financial conflict of interest (FCOI) exists. Through the COI Risk Manager online system, the Office of Research Compliance and Assurance is notified for positive responses on a Conflict of Interest disclosure form.
- (2) Determine if the FCOI could directly and significantly affect the design, conduct, or reporting of the research. The term “significantly” in this context means that the financial interest would have a material effect on the research, which we believe appropriately fulfills the intent of the regulations, i.e., to maintain objectivity in PHS funded research.
- (3) The Office of Research Compliance and Assurance must determine whether the *financial interest* is **related** to the investigator’s research. A *financial interest* is related to the research when the interest could be affected by the research; or is in an entity whose financial interest could be affected by the research results and outcomes. The institution is required to report all FCOIs related to PHS studies to the funding agency.
- (4) The Office of Research Compliance and Assurance, in consultation with the Investigator, will determine appropriate mitigation measures to manage, reduce, or eliminate the *financial interest* by requiring a management plan to ensure the research is free from bias or financial conflicts resulting from investigator’s *financial interests*.

The following factors shall be considered in the review process:

- Financial interest is affiliated in an entity that is part of a consortium or will otherwise participate in the research.
- The investigator is involved in research under a subaward from an entity in which he/she has a financial interest.
- Entity in which the investigator has a financial interest is a sub-recipient under the research
- The investigator has a financial interest in an entity which research space is or will be leased or from which research space will be rented.
- Intellectual property developed by the investigator is being used, tested or further developed in the research.
- Intellectual property owned by the institution and optioned/licensed to an entity in which the investigator has a financial interest is being used, tested or further developed in the research.
- Financial interest is affiliated in an entity whose products/services are related to the subject of the research, but research subjects will not receive treatment using the entity’s products.
- Products/services are being provided by or purchased from a company in which the investigator has a financial interest.
- The investigator has a financial interest in a company which manufactures or sells a concomitant or comparator drug or device, or procedure.
- The investigator is a founder of, holds a management /executive position with, serves on a Board of, is a consultant to (with or without compensation), and/or has received travel income/reimbursement from an entity whose products or services will be used in, are the subjects of and/or closely aligned with the research.