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

(1) The university designated official(s) (Department Chair or Supervisor) reviews financial conflict of interest disclosures to determine if a financial conflict of interest (FCOI) exists.

(2) Determine if the FCOI could directly and significantly affect the design, conduct, or reporting of the research.

(3) The designated official(s) 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.

(4) The designated official(s), 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 designated official (departmental chair or supervisor) and Office of Research Compliance shall consider, but not limited to, the following factors:

- 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 an financial interest.
- Entity in which the investigator has an 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 us 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 manufacturers 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 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.

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