

**UPMC POLICY ON MANAGEMENT OF CONFLICT OF INTEREST FOR RESEARCH REGULATED BY
PUBLIC HEALTH SERVICE CONFLICT OF INTEREST REQUIREMENTS**

In addition to provisions of other UPMC policies HS-EC 1700 (COI: General Obligations) and HS-EC 1701 (Conflicts of Interest in Clinical Research), research requiring compliance with Public Health Service conflict of interest (COI) requirements must also comply with the following policy:

1. Definition of a Significant Financial Interest: A Significant Financial Interest is a financial interest (i.e., anything of monetary value, whether or not the value is readily ascertainable) consisting of one or more of the following interests of the Investigator (and Members of the Immediate Family) that reasonably appear to be related to the Investigator's institutional responsibilities:

- a. the aggregation of remuneration received from any publicly traded entity in the 12 months preceding the disclosure (including salary, consulting fees, honoraria, and paid authorship) and the value of any equity interest in that entity as of the date of disclosure (including any stock, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value) exceeding \$5,000¹;
- b. any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure exceeding \$5,000, or any equity interest in such an entity (e.g., stock, stock option, or other ownership interest);
- c. being the inventor of a technology that has been patented, copyrighted or optioned/ licensed to an external entity, and on which research is continuing;
- d. any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to institutional responsibilities, except travel that is reimbursed or sponsored by 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 [Exempt Institutions].

The term SFI does not include

- a. salary or supplementary payments from the University of Pittsburgh, University of Pittsburgh Medical Center (UPMC), University of Pittsburgh Physicians (UPP), or Veterans Administration Pittsburgh Healthcare System;
- b. income from seminars, lectures, or non-promotional engagements sponsored by Exempt Institutions;
- c. income from service on advisory committees or review panels for Exempt Institutions;
- d. royalties, milestone payments, or licensing fees paid through the University of Pittsburgh;
- e. income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

¹ This figure reflects the SFI threshold established by the federal government's regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94.

2. Disclosure: Individuals who have applied for or received funding subject to PHS COI requirements in the previous 12 months, or expect to receive such funding in the next 12 months, will be informed of UPMC's policies related to financial conflicts of interest and will be required to disclose the following information:

- a) offices and positions in an entity whose interests would reasonably appear to be affected by their research;
- b) remunerative activities constituting an SFI in an external entity, and the amount of the remuneration;
- c) outside employment of students and staff;
- d) technology transfer activities, including patents awarded and copyrights registered;
- e) other financial transactions;
- f) ownership constituting an SFI in an external entity, and the value of the equity held.
- g) conflicts relating to federal or industry-supported research
- h) reimbursed or sponsored travel related to their institutional responsibilities: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Ethics and Compliance Committee of the UPMC Board of Directors or its delegates have the right to request additional information, including a determination or disclosure of the monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Investigators will be required to make annual and transactional disclosures as described in Policy HS-EC1701. Investigators will be informed of their responsibilities related to disclosure and management of conflict of interest at least every 4 years.

3. Training: Each investigator is required to complete a COI training module prior to engaging in research subject to PHS COI requirements, again every three years, and at other times, as directed by the UPMC Ethics and Compliance Office.

4. Review of Disclosures: Disclosure information will be placed into the UPMC Watchlist and queried by UPMC OSPARS at the time of project submission and project contracting, as well as on an annual basis. All SFI's greater or equal to \$5,000 will be reviewed by OSPARS and the delegate(s) of the UPMC Board of Directors Ethics and Compliance Committee to determine if a Financial Conflict of Interest (FCOI) exists, based on its relatedness to the PHS-funded research. The results of this review will be documented, with an explanation as to why there is no FCOI or stating that there is a FCOI and indicating what level of management will be required. Conflict management plans will be developed and overseen in accord with UPMC Policy HS-EC1701.

5. Recording and Monitoring of FCOI's: A report will be completed on each FCOI, to include: the name of the investigator, the title of the investigator and role on the respective research project, name of the entity in which interests are held, nature of the SFI, description of the management plan, and approximate dollar amount of the SFI. Annual FCOI reports will be submitted for the duration of the PHS-funded research project addressing the status of the FCOI and any changes to the management plan.

6. Monitoring of FCOI of Sub-Recipient Investigators: All subcontracts of PHS-funded research shall specify whether the FCOI policy of the sub-recipient or UPMC will apply to the sub-recipient's investigators. If the sub-recipient's policy will be applied, the agreement must include a certification that the policy complies with the PHS regulations. In either case, the contract must specify time periods for disclosures, management, and reporting of FCOI's.

7. Retrospective Review: In case of delay in identifying or managing a FCOI, or failure of the investigator to comply with a plan to manage his/her FCOI, UPMC shall, within 120 days of determination of non-compliance, complete a retrospective review to determine if PHS-funded research was biased in the design, conduct, or reporting of such research during the period of non-compliance.

8. Public Accessibility: Upon requests for information about SFI's, UPMC will provide written responses within 5 business days on existing disclosures of SFI's that are related to PHS-funded research and are deemed to be FCOI's. Information provided will include the investigator's name, investigator's title and role on the research project,

name of the entity in which the SFI is held, the nature of the SFI, and the approximate dollar amount (or a statement that the interest is one whose value cannot be readily determined).