



TITLE: **Financial Conflicts of Interest of Investigators and Research Staff**

PURPOSE: Define process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research to the Institutional Review Committee (IRC).

RESPONSIBILITIES: The Conflict of Interest Program (COI) in collaboration with the HSPP, IRB, and COI staff.

PROCEDURES:

When an investigator or research staff has reported a financial interest *Related to the Research* to the IRB or IRC, review the reported financial interest and the research protocol.

If the financial interest and research protocol have already been reviewed by the IRC and, if needed, managed, notify the HSPP staff in writing.

Determination of a Financial Conflict of Interest

If the financial interest and research protocol have not been reviewed, COI will do so to determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting of the Human Research.

If there is no conflict of interest, notify the HSPP staff of this determination in writing.

If there is an identified FCOI involving an Investigator working on a human subjects research project

- Notify HSPP within five (5) business days of the conflict
- Recommend to the IRB under what circumstances, if any, the conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:
 - Subject recruitment
 - Prescreening for inclusion/exclusion criteria
 - The consent process
 - The treatment of subjects, separate from the research interventions or procedures
 - Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting

Management Plan

The Conflict of Interest Program and HSPP will coordinate the development of management plans to include the following options:

- Public disclosure of the financial interests.
- Monitoring of research by independent reviewers.
- Modification of the research plan.
- Disqualification from participation in all or a portion of the Human Research.
- Divestiture of financial interests.
- Severance of relationships that create the conflict of interests.



- Use of an external IRB.

Following the development of the draft development plan:

- The IRB Chair and HSPP Director will review the draft plan with the Senior Vice President for Research (SVPR).
- The SVPR will present the draft plan to and address questions of the IRB during a duly convened meeting.
- The IRB will determine whether the management plan allows the research to proceed or be approved.

Records Retention

Provide the final, approved management plan to the SVPR and COI Program for final implementation. When required, provide the final determination to funding or regulatory agencies. Maintain a copy of determinations and management plans in the records.

MATERIALS:

None

REFERENCES:

- OHRP Guidance Document, “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,” dated May 5, 2004.
- UA Individual Conflict of Interest and Conflict of Commitment Policy

REVIEW/REVISIONS:

From 10/01/10 version: Clarified role of the IRB in deciding if Financial Conflict of Interest management plans are appropriate and whether the research may be conducted (AAHRPP Element I.6.A).

From 01/2014 version: Renumbered from P&P-055.