



## SOP: Management of Financial Interests

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### 1. PURPOSE

- 1.1. This procedure establishes the process to evaluate and manage financial interests <Related to the Research>.
- 1.2. This procedure begins when an individual or the [Organization] discloses a financial interest <Related to the Research>.
- 1.3. This procedure ends when the [Conflicts of Interests Officer] decides that the financial interest is not a conflict of interest, or informs the IRB of the management plan.

### 2. POLICY

- 2.1. For any or all steps of this procedure, the [Conflicts of Interests Officer] may have the Conflicts of Interests Committee follow the procedure whenever the [Conflicts of Interests Officer] believes that institutional consensus is needed to make a decision.
- 2.2. The financial disclosure threshold may not vary by funding or regulatory oversight.
- 2.3. Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
  - 2.3.1. The design, conduct, or reporting of research
  - 2.3.2. Research consultation
  - 2.3.3. Teaching
  - 2.3.4. Professional practice
  - 2.3.5. Institutional committee memberships
  - 2.3.6. Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards
- 2.4. Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
  - 2.4.1. Joining the [Organization]
  - 2.4.2. Financial conflicts policies are revised in a manner that changes investigator requirements
  - 2.4.3. Non-compliant with financial conflicts policies and procedures
- 2.5. Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
- 2.6. Significant financial interest means:
  - 2.6.1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    - 2.6.1.1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
    - 2.6.1.2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);



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- 2.6.1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- 2.6.1.4. Compensation of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
- 2.6.1.5. Board or executive relationship.
- 2.6.2. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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.
- 2.7. Violations of this policy or proscribed management plans can lead to:
  - 2.7.1. Loss or restriction of privileges to conduct research
  - 2.7.2. Other employment actions as allowed by Human Resources Policies and Procedures.
- 2.8. Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.
- 2.9. The IRB has the authority to decide whether a financial interest and its management, if any, allow the research to meet criteria for approval.

### 3. RESPONSIBILITY

- 3.1. [Conflicts of Interests Officer] carries out these procedures.
- 3.2. If the [Conflicts of Interests Officer] needs the input of the Conflicts of Interests Committee to make a determination, the [Conflicts of Interests Officer] can have that committee carry out these procedures.

### 4. PROCEDURE

- 4.1. Ensure individuals do not participate in the review of any conflict of interests in which the individual has <Conflicting Interest>.
- 4.2. Review the reported financial interest and the research.
- 4.3. If the [Organization] has already reviewed the financial interest and research, notify the HRPP staff member handling the submission and stop processing this SOP.
- 4.4. Determine whether the reported financial interest is <Related to the Research>.
  - 4.4.1. If the financial interest is not <Related to the Research>, notify the HRPP staff member handling the submission and stop processing this SOP.



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- 4.5. Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the research.
  - 4.5.1. If there is no conflict, notify the HRPP staff member handling the submission and stop processing this procedure.
- 4.6. Use “WORKSHEET: Financial Interest Management (HRP-412)” and work with the investigator to develop a written management plan.
- 4.7. Provide the HRPP staff member handling the submission with the written management plan.
- 4.8. When required provide the final determination to the funding or regulatory agencies.
- 4.9. Maintain a copy of determinations and management plans in the records.

## 5. REFERENCES

- 5.1. 42 CFR §50
- 5.2. 45 CFR §94