



**SOP: Financial Conflicts of Interests**

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**1 PURPOSE**

- 1.1 This procedure establishes the 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.
- 1.2 The process begins when Office of Research Compliance or HSRO determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institutional financial interest Related to the Research.
- 1.3 The process ends when the Office of Research Compliance or the Conflict of Interest Committee has evaluated the reported interest and communicated the results of this evaluation to the IRB.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 GUIDING PRINCIPLES**

- 3.1 The Vice Provost for Research serves as the chief administrative officer and has been designated by the Provost to solicit and review disclosures of potential conflicts of interest related to the research, scholarly and educational activities at the University of Miami.
- 3.2 For any or all steps of this procedure, the Vice Provost for Research may have the Conflict of Interest Committee follow the procedure whenever the Vice Provost for Research believes that institutional consensus is needed to make a decision.
- 3.3 The financial disclosure threshold may not vary by funding or regulatory oversight.
- 3.4 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
  - 3.4.1 The design, conduct, or reporting of research
  - 3.4.2 Research consultation
  - 3.4.3 Teaching
  - 3.4.4 Professional practice
  - 3.4.5 Institutional committee memberships
  - 3.4.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards
- 3.5 Individuals subject to this policy are required to complete conflicts of interest training initially, at least every four years, and immediately when:
  - 3.5.1 Joining the organization
  - 3.5.2 Financial conflict policies are revised in a manner that changes investigator requirements
  - 3.5.3 Non-compliant with financial conflict policies and procedures
- 3.6 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and their financial and obligatory interests related to his/her institutional responsibilities:
  - 3.6.1 On submission of an initial study application for IRB review.
  - 3.6.2 At least annually on submission of continuing review.
  - 3.6.3 Upon acquiring a position or assignment to an institutional responsibility that is subject to this policy.
  - 3.6.4 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial or obligatory interest



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- 3.7 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the monetary value, the destination, and the duration.
- 3.8 Significant Financial Interest means 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:
  - 3.8.1 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;
  - 3.8.2 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); or
  - 3.8.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income aggregated at \$5,000 or more from one entity for said rights and interests.
- 3.9 Violations of this policy or proscribed management plans can lead to:
  - 3.9.1 Loss or restriction of privileges to conduct research
  - 3.9.2 Other employment actions as allowed by Human Resources Policies and Procedures.
- 3.10 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.

**4 RESPONSIBILITIES**

- 4.1 The Vice Provost for Research carries out these procedures or ensures that a committee follows these procedures.

**5 PROCEDURE**

- 5.1 Ensure committee members do not participate in the review of any conflicts of interest in which the member has Conflicting Interest.
- 5.2 Review the reported financial interest and the research protocol.
  - 5.2.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the HSRO staff of this determination in writing and the procedure ends here.
- 5.3 Determine whether the reported financial interest is related to the research.
  - 5.3.1 If the financial interest is not related to the research, notify the HSRO staff of this determination in writing and this procedure ends here.
- 5.4 Determine whether the reported financial interest could directly and substantially affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interest) of the Human Research.
  - 5.4.1 If there is no conflict of interest, notify the HSRO staff of this determination in writing and this procedure ends here.



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- 5.5 If a conflict of interest exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:
    - 5.5.1 Subject recruitment.
    - 5.5.2 Prescreening for inclusion/exclusion criteria.
    - 5.5.3 The consent process.
    - 5.5.4 The clinical treatment of subjects, separate from the research interventions or procedures.
    - 5.5.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
  - 5.6 Create a written management plan, considering the following options:
    - 5.6.1 Public disclosure of the financial interests.
    - 5.6.2 Disclosure of the financial interests to subjects.
    - 5.6.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.
    - 5.6.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
    - 5.6.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
    - 5.6.6 Severance of relationships that create financial conflicts.
    - 5.6.7 Modification of the research plan.
    - 5.6.8 Involvement of external individuals in key portions of the protocol
    - 5.6.9 Use of an external IRB.
    - 5.6.10 A retrospective review.
    - 5.6.11 A mitigation report.
    - 5.6.12 A plan to monitor and enforce the implementation of the management plan.
  - 5.7 Provide the written management plan to the conflicted individual or office for comment and review.
  - 5.8 Finalize the written management plan.
  - 5.9 Provide the HSRO staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.
  - 5.10 When required provide the final determination to the funding or regulatory agencies.
  - 5.11 Maintain a copy of determinations and management plans in the records.
- 6 MATERIALS**
- 6.1 None
- 7 REFERENCES**
- 7.1 42 CFR §50
  - 7.2 45 CFR §94