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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 Institution discloses a financial interest Related to the Research.
- 1.3. This procedure ends when the [Conflicts of Interests Officer] and others, as needed 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 others, as needed, 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; or
 - 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 Institution;
 - 2.4.2. Financial conflicts policies are revised in a manner that changes investigator requirements; or
 - 2.4.3. Non-compliant with financial conflicts policies and procedures.
- 2.5. Investigators are required to complete PHS FCOI Reimbursed or Paid Travel Disclosure Form (DSP-05: PHS) in order to disclose any reimbursed or sponsored (except when paid through the institution) travel related to institutional responsibilities.
 - 2.5.1. Not required to be disclosed is travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - 2.5.2. 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 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. 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;

- 2.6.2. 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
- 2.6.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2.7. Violations of this policy or proscribed management plans can lead to:
 - 2.7.1. Loss or restriction of privileges to conduct research; and/or
 - 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.

4. PROCEDURE

- 4.1. Ensure individuals do not participate in the decision-making regarding any conflict of interest in which the individual has a Conflict of Interest.
- 4.2. Review the reported financial interest and the research.
- 4.3. If the Institution has already reviewed the financial interest and research, notify the IRB staff member handling the submission and stop processing under this Policy.
- 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 IRB staff member handling the submission and stop processing under this Policy.
- 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 interest) of the research.
 - 4.5.1. If there is no conflict, notify the IRB staff member handling the submission and stop processing this procedure.
- 4.6. Reference "[IRB REGULATORY GUIDANCE: Financial Interest Management \(HRP-412\)](#)" and work with the investigator to develop a written management plan.
- 4.7. Provide the IRB staff member handling the submission with the written management plan through MyIRB.
- 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.
- 4.10. Periodic monitoring includes the appropriate college representative meeting yearly with the Investigator with the Conflict of Interest to discuss any changes and compliance. The Investigator with the Conflict of Interest also submits a yearly report. The Conflict of Interest Officer reviews the yearly report for compliance.
 - 4.10.1. Additionally, Chair of the Investigator with the Conflict of Interest or others may inform the Conflict of Interest Officer or the college representative of concerns. The IRB does audits and notifies the Conflict of Interest Officer of concerns.

5. REFERENCES

POLICY: Management of Financial Interests

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- 5.1. 42 CFR §50
- 5.2. 45 CFR §94
- 5.3. UF Guidelines, Policies, and Procedures on Conflict of Interest and Outside Activities, including Financial Interest Website:
<http://generalcounsel.ufl.edu/media/generalcounselufledu/documents/COI.pdf>
- 5.4. UF Office of Research Conflict of Interest Webpage: <http://research.ufl.edu/faculty-and-staff/research-compliance/conflict-of-interest-and-outside-activities.html>