

Standard Operating Procedure (SOP)

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| SOP #: 401.120 | HRP-120 Management of Financial Interests |
| Executive Owner: Vice President Research Operations | Effective Date: 6/11/2018 |
| | Review Date: 09/23/2019 |

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| Scope | This standard operating procedure (SOP) applies to the HRPP staff members at AdventHealth Orlando. |
| Purpose | This procedure establishes the process to evaluate and manage financial interests <Related to the Research>. This procedure begins when an individual or the [Organization] discloses a financial interest <Related to the Research>. This procedure ends when the [Conflicts of Interest Officer] decides that the financial interest is not a conflict of interest, or informs the IRB of the management plan. |
| Qualified Personnel | The [Conflicts of Interest Officer] carries out these procedures. |
| Training | Not applicable. |
| Supplies & Equipment | Not applicable. |
| Procedure | <ol style="list-style-type: none"> 1. Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following: <ol style="list-style-type: none"> 1.1. The design, conduct, or reporting of research 1.2. Research consultation 1.3. Teaching 1.4. Professional practice 1.5. Institutional committee memberships 1.6. Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards 2. Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when: <ol style="list-style-type: none"> 2.1. Joining the [Organization] 2.2. Financial conflicts policies are revised in a manner that changes investigator requirements 2.3. Non-compliant with financial conflicts policies and procedures 3. Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. 4. 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: <ol style="list-style-type: none"> 4.1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from |

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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;

- 4.2. 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
- 4.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
5. Financial Conflict of Interest Management Plans are developed and managed using POLICY: Financial Conflict of Interest in Research – Individual HRP-400.005” and “SOP: Financial Conflict of Interest in Research – Individual HRP-403.001.
6. Violations of this policy (400.005) or proscribed management plans can lead to:
 - 6.1. Loss or restriction of privileges to conduct research
 - 6.2. Other employment actions as allowed by Human Resources Policies and Procedures.
7. The IRB has the authority to decide whether a financial interest and its management plan, as reported to the IRB by the [Conflicts of Interest Officer], allows the research to meet criteria for approval.
8. Follow POLICY: Financial Conflict of Interest in Research – Individual HRP-400.005” and “SOP: Financial Conflict of Interest in Research – Individual HRP-403.001
9. Use WORKSHEET: Financial Interest Management (HRP-412) and work with the investigator to develop a written management plan.
 - 9.1. Report the results of the management plan to the IRB.

Definition(s)

IRB: Institutional Review Board

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| Reference(s) | HRPP: Human Research Protection Program 42 CFR §50 45 CFR §94 |
| Related Documents | Not applicable. |
| Keywords | IRB, institutional review board, IRB member |