



Tampa General Hospital POLICY & PROCEDURE

Organizational Hospital Ambulatory Services Departmental

Title: Investigator Conflicts of Interest for Research

Original Issue Date: 7/15/2019

Number: OCR-255

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Review Date:

Revision Date:

Originating Department: Office of Research Compliance

Approved by: Sally Houston, MD

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 the Office of Clinical Research (OCR) determines that an investigator or research staff has reported a financial interest Related to the Research or the OCR staff have detected an institution financial interest Related to the Research.
- 1.3 The process ends when the Office of Research Compliance, or the Conflict of Interest (COI) Determination Committee has evaluated the reported interest and communicated the results of this evaluation to the reviewing IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Research Compliance Officer serves as the COI Officer for Research.
- 3.2 For any or all steps of this procedure, the COI Officer may have the COI Determination Committee follow the procedure whenever the COI Officer believes that institutional consensus is needed to make a decision.
- 3.3 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
 - 3.3.1 The design, conduct, or reporting of research
 - 3.3.2 Research consultation
 - 3.3.3 Teaching
 - 3.3.4 Professional practice
 - 3.3.5 Institutional committee memberships
 - 3.3.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards
- 3.4 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
 - 3.4.1 Joining the organization
 - 3.4.2 Financial conflicts policies are revised in a manner that changes investigator requirements
 - 3.4.3 Non-compliant with financial conflicts policies and procedures
- 3.5 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:
 - 3.5.1 On submission of an initial review.

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- 3.5.2 At least annually on submission of continuing review.
- 3.5.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest
- 3.6 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
- 3.7 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:
 - 3.7.1 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;
 - 3.7.2 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
 - 3.7.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 3.8 Violations of this policy or proscribed management plans can lead to:
 - 3.8.1 Loss or restriction of privileges to conduct research
 - 3.8.2 Other employment actions as allow by Human Resources Policies and Procedures.
- 3.9 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 COI Officer carries out these procedures or ensures that the COI Determination Committee follows these procedures.

5 PROCEDURE

- 5.1 Review the reported financial interest and the research protocol.
 - 5.1.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.2 Determine whether the reported financial interest is related to the research.
 - 5.2.1 If the financial interest is not related to the research, notify the reviewing IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.3 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 Human Research.
 - 5.3.1 If there is no conflict of interests, notify the reviewing IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.4 If a conflict of interests 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:
 - 5.4.1 Subject recruitment.
 - 5.4.2 Prescreening for inclusion/exclusion criteria.

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- 5.4.3 The consent process.
- 5.4.4 The clinical treatment of subjects, separate from the research interventions or procedures.
- 5.4.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
- 5.5 Create a written management plan, considering the following options:
 - 5.5.1 Public disclosure of the financial interests.
 - 5.5.2 Disclosure of the financial interests to subjects.
 - 5.5.3 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.
 - 5.5.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
 - 5.5.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - 5.5.6 Severance of relationships that create financial conflicts.
 - 5.5.7 Modification of the research plan.
 - 5.5.8 Involvement of external individuals in key portions of the protocol
 - 5.5.9 Use of an external IRB.
 - 5.5.10 A retrospective review.
 - 5.5.11 A mitigation report.
 - 5.5.12 A plan to monitor and enforce the implementation of the management plan.
- 5.6 Provide the written management plan to the involved individual or office for comment and review.
- 5.7 Finalize the written management plan.
- 5.8 Provide the IRB 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.
- 5.9 When required provide the final determination to the funding or regulatory agencies.
- 5.10 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