1 PURPOSE

1.1 This procedure describes the process to evaluate a report of a financial interest of an investigator or research staff involved with Human Research or an institutional financial interest Related to the Research.

1.2 The process begins when:

1.2.1 The COI Office determines that an investigator or research staff has reported a financial interest Related to the Research or;

1.2.2 IRB staff notify the COI Officer that an investigator or research staff involved with Human Research has reported a financial interest Related to the Research, or;

1.2.3 IRB staff detect an institutional financial interest Related to the Research and notify the COI Office.

1.3 The process ends when the COI Office has evaluated the reported interest and communicated the results of this evaluation to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revisions for AAHRPP accreditation, replaces version dated 06/19/2009

3 POLICY

3.1 The Director of Research Compliance serves as the COI Officer.

3.2 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.

3.3 The financial disclosure threshold may not vary by funding or regulatory oversight.

3.4 Individuals generally may not conduct clinical research with human participants if they have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions are permitted only if the conflict of interest committee (a) determines that an individual's participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research.

3.5 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:

3.5.1 The design, conduct, or reporting of research
3.5.2 Research consultation
3.5.3 Teaching
3.5.4 Professional practice
3.5.5 Institutional committee memberships
3.5.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

3.6 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

3.6.1 Joining the organization
3.6.2 Financial conflicts policies are revised in a manner that changes investigator requirements
3.6.3 Non-compliant with financial conflicts policies and procedures

3.7 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:

3.7.1 On submission of an initial review.
3.7.2 At least annually on submission of continuing review.
3.7.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest

3.8 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

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 allow 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.

3.11 For the purposes of this standard operating procedure:

3.11.1 "Related to the Research" means a financial interest in the sponsor, in a competitor of the sponsor, in the product or service being tested, or in a product or service that competes with the product or service being tested.

3.11.2 "Immediate Family" means an individual’s spouse and dependent children.

3.11.3 "Equity Interest" means any stock, debt obligation, or derivative thereof, including options, exclusive of diversified mutual funds. (e.g., stocks, stock options or other ownership interests);

3.11.4 "Non-Publicly Traded Corporation" means a corporation not listed on the New York Stock Exchange (NYSE), the American Stock Exchange (AMEX), or National Association of Security Dealers Automated Quotations (NASDAQ).

3.11.5 "Compensation" means any payment including salary, bonus, fees, honorarium, royalties, or in kind products or services including royalties from University of Central Florida, but excluding:

3.11.5.1 Salary and other non-royalty compensation from University of Central Florida.

3.11.5.2 Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.

3.11.5.3 Income from service on advisory committees or review panels for public or nonprofit entities.

3.11.6 "Intellectual Property Rights" means patents, copyrights, trademarks, or the right to royalties from such rights.

3.12 The following financial interests require review by a conflicts of interests committee:

3.12.1 Compensation Related to the Research that when aggregated for the investigator and the investigator’s Immediate Family are expected to exceed $5,000 in any calendar year.

3.12.2 Compensation Related to the Research of any amount to the investigator or any member of the individual’s Immediate Family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.

3.12.3 Equity Interest Related to the Research whose value when aggregated for the individual and the individual’s Immediate Family exceeds $5,000.

3.12.4 Equity Interest Related to the Research whose value when aggregated for the individual and the individual’s Immediate Family represents more than a five percent ownership interest in any single entity.

3.12.5 Equity Interest Related to the Research in a Non-Publicly Traded Corporation of any value by the individual or a member of the the individual’s Immediate Family.

3.12.6 Equity Interest Related to the Research of any amount to the investigator or any member of the individual’s Immediate Family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.

3.12.7 Intellectual Property Rights Related to the Research held by the individual or the individual’s immediate family likely to result in royalties that will exceed $5,000 per year.
3.12.8 Board, executive, or fiduciary interest Related to the Research.

4 RESPONSIBILITIES

4.1 The COI Officer carries out these procedures or ensures that a 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 financial interest and research protocol has already been processed under this standard operating procedure.

5.2.1 If yes, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

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 IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.4 Determine whether the financial interest is prohibited under Florida law or requires an exemption.

5.4.1 If the financial interest is prohibited under Florida State law, notify the investigator of this determination and stop processing subsequent steps of this procedure.

5.4.2 If the financial interest requires a Florida State exemption, take steps to obtain an exemption and then process the subsequent steps of this procedure.

5.5 Determine whether the financial interest falls within one or more categories of financial interest that requires review by a committee.

5.5.1 If the financial interest does not require review by a committee, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.6 Convene a conflicts of interests committee meeting of at least five individuals to review the financial interest.

5.6.1 Exclude individuals who:

5.6.1.1 Have a fiduciary or promotional relationship Related to the Research.

5.6.1.2 Are involved in the design, conduct, or reporting of the research and individuals.

5.6.1.3 Are involved in competing research.

5.6.2 Include:

5.6.2.1 At least one, but no more than two, individuals from the investigator’s department.

5.6.2.2 At least one individual not affiliated with the institution.

5.7 Provide the committee members with a description of the financial interest, a copy of the protocol, and supporting documents to review.

5.8 Have the committee follow these steps:

5.8.1 Determine whether the reported financial interest is related to the research.

5.8.1.1 If the financial interest is not related to the research, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.8.2 Review the financial interest in the context of the research protocol.

5.8.3 Determine the likelihood of that the financial interest could directly and significantly affect the design, conduct, or reporting of the Human Research
5.8.3.1 Consider the following questions:
   5.8.3.1.1 What is the value of the financial interest?
   5.8.3.1.2 What is the scope of the relationship?
   5.8.3.1.3 What is the extent of discretion?

5.8.3.2 If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.8.4 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:
   5.8.4.1 Subject recruitment?
   5.8.4.2 Prescreening for inclusion/exclusion criteria?
   5.8.4.3 The consent process?
   5.8.4.4 The treatment of subjects, separate from the research interventions or procedures?
   5.8.4.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting?

5.8.5 Devise and implement a plan to eliminate, reduce, or manage the conflict of interests, considering at a minimum the following options:
   5.8.5.1 Public disclosure of the financial interests.
   5.8.5.2 Disclosure of the financial interests to subjects.
   5.8.5.3 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.
   5.8.5.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
   5.8.5.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
   5.8.5.6 Severance of relationships that create financial conflicts.
   5.8.5.7 Modification of the research plan.
   5.8.5.8 Involvement of external individuals in key portions of the protocol
   5.8.5.9 Use of an external IRB.
   5.8.5.10 A retrospective review.
   5.8.5.11 A mitigation report.
   5.8.5.12 A plan to monitor and enforce the implementation of the management plan.

5.9 Provide the management plan to the investigator for comment and review.

5.10 Finalize the written management plan.

5.11 Provide the IRB staff 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.

5.12 When required provide the final determination to the funding or regulatory agencies.

5.13 Maintain a copy of determinations and management plans in the records.

6 MATERIALS
   6.1 None

7 REFERENCES
   7.1 None