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 Research Conflict of Interest Committee determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institution financial interest Related to the Research.

1.3 The process ends when the Research 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 Added references to financial disclosure policies; replaced version dated 8/23/2013.

3 POLICY

3.1 The Director of the Office of Research and Technology Development serves as the Conflicts of Interest (COI) Officer.

3.2 For any or all steps of this procedure, the COI Officer may have the Research Conflict of Interest Committee follow the procedure whenever the COI Officer believes that institutional consensus is needed to make a decision.

3.3 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.

4 RESPONSIBILITIES

4.1 The COI Officer carries out these procedures or ensures that the Research Conflict of Interest 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 could directly and significantly affect the design, conduct, or reporting of the Human Research.

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

5.3 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:

5.3.1 Subject recruitment?

5.3.2 Prescreening for inclusion/exclusion criteria?

5.3.3 The consent process?

5.3.4 The treatment of subjects, separate from the research interventions or procedures?

5.3.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting?

5.4 Create a written management plan, considering the following options:

5.4.1 Public disclosure of the financial interests.

5.4.2 Monitoring of research by independent reviewers.

5.4.3 Modification of the research plan.

5.4.4 Disqualification from participation in all or a portion of the Human Research.

5.4.5 Divestiture of financial interests.
5.4.6 Severance of relationships that create the conflict of interests.
5.4.7 Involvement of external individuals in key portions of the protocol
5.4.8 Use of an external IRB.

5.5 Provide the written management plan to the involved individual or office for comment and review.
5.6 Finalize the written management plan.
5.7 Provide the IRB staff with the written management plan.
5.8 When required provide the final determination to the funding or regulatory agencies.
5.9 Maintain a copy of determinations and management plans in the records.

6 MATERIALS
6.1 A0283.1 Financial Interest for PHS policy

7 REFERENCES
7.1 None