Title: Financial Conflicts of Interests

SOP # HRP-055

Revision # 1

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Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC

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Approved: Richard Larson, MD PhD Vice Chancellor for Research

Date: 11/19/14

1 PURPOSE
1.1 This procedure establishes the process to evaluate a report of financial interest of an investigator or research staff related to the individual’s institutional responsibilities or an institutional financial interest to determine whether or not it is Related to the Research.

1.2 The process begins when the COI Office determines that an investigator or research staff has reported a financial interest related to the individual’s institutional responsibilities.

1.3 The process ends when the COI Office has evaluated the reported interest, determined whether or not the financial interest is Related to the Research and if the interest constitutes a potential Conflict of Interest requiring a management plan. Results of this evaluation are then communicated to the HRRC.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Complete revision of SOP to align with current practice.

3 POLICY
3.1 The Conflicts of Interest Operations Manager serves as the Conflicts of Interests 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 are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
3.4.1 The design, conduct, or reporting of research
3.4.2 Research consultation
3.4.3 Teaching
3.4.4 Professional practice
3.4.5 Institutional committee memberships
3.4.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

3.5 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
3.5.1 Joining the organization
3.5.2 Financial conflicts policies are revised in a manner that changes investigator requirements
3.5.3 Non-compliant with financial conflicts policies and procedures
3.6 Individuals subject to this policy are required to disclose their financial interests related to their institutional responsibilities:
3.6.1 On submission of an HRRC initial review application.
3.6.2 On submission of a contract or grant application.
3.6.3 At least annually for sponsored studies.
3.6.4 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
3.7 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
3.8 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:
3.8.1 With regard to any publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the twelve months preceding the disclosure and/or any equity interest in the entity as of the date of disclosure. 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;
3.8.2 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
3.8.3 Intellectual property rights and interests (e.g., patents, copyrights) other than through UNM or STC.UNM, upon receipt of income related to such rights and interests.
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 The COI review determination and management plan, if applicable, will be considered as part of the final HRRC determination for approval of research. The HRRC may accept the plan as sufficient, add requirements to the management plan, or determine that the conflict and/or management plan is such that the research cannot be approved as proposed.

4 RESPONSIBILITIES
4.1 The COI Officer carries out these procedures or ensures that the COI committee follows these procedures.

5 PROCEDURE
5.1 Ensure COI committee members do not participate in the review of any conflict of interests in which the member has Conflicting Interest.

5.2 Review the reported financial interest and the research protocol.
   5.2.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the HRPO 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 HRPO 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.
   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.
   5.4.6 Data collection and/or analysis

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 HRPO staff of the reviewing HRRC with the written management plan so the HRRC can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved. The HRRC can also
revise the management plan to be stricter than stated by the COI Committee but it cannot be revised to be less strict.

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