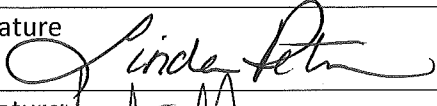
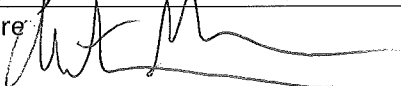




Standard Operating Procedures		
<b>SOP #504.1 Revision 1</b>	<b>TITLE: Researcher Conflict of Interest Coordination</b>	Effective Date: 1/18/2017
Approved By: OIRB Director	Signature 	Date 1/23/2017
Approved By: IRB Chair	Signature 	Date 1/23/2017

**PURPOSE**

To describe the policies and procedures for identifying and managing any significant financial or personal conflict of interest (COI) held by UNM researchers that could affect research involving human subjects.

**REVISIONS FROM PREVIOUS VERSION**

Add examples of situations which could identify COI; clarification of when IRB approval is withheld pending COI review

**POLICY**

Human subject research protocols shall be reviewed for potential conflicts of interest involving possible financial gain or other personal advantage to persons associated with the research. Researchers are required to disclose potential COI annually and during the research process, should there be a material change or a submission to the Public Health Service (PHS). Willful failure to disclose a significant COI is a violation of UNM policy.

COI may arise in several forms but most commonly involve explicit or anticipated financial benefit to the researcher. The benefit may be direct payment or it may be indirect, such as through ownership interest in a firm that may benefit from a particular outcome of the research. A conflict of interest also may exist for a researcher’s immediate family member(s) or life partner who could potentially benefit in such ways from the research results.

All researchers, including students, must submit a COI disclosure prior to submission to the OIRB including:

- a) significant financial interest that could directly and significantly affect the design, conduct or reporting of UNM research activities; or
- b) any situation that could directly and significantly affect the design, conduct or reporting of human research activities or his/her professional commitments or allegiance to UNM. These situations may include but are not limited to family collaborations on the study, outside employment in a field similar or directly related to the research, and committee/board member roles similar or directly related to the research.

Disclosures will be reviewed by the UNM Conflict of Interest (COI) committee per UNM Policy E110: Conflicts of Interest in Research. Disclosure may not be sufficient to discharge the conflict; in some cases



the UNM COI Committee may direct the researcher to divest of some or all financial interests in the conflicting entity or to withdraw from the research project as a researcher. All COI management plans and decision memos with stipulations implemented by the COI Committee for individuals involved in human research will be provided to the IRB for review by the researcher as part of the IRB submission process.

## **RESPONSIBILITIES**

Execution of SOP: Researchers, OIRB Staff, UNM COI Committee.

## **PROCEDURE**

### *IRB Review of the COI Decision Memos and Management Plans*

1. The IRB is responsible for reviewing all COI management plans and decision memos (with stipulations) issued by the COI Committee to ensure that there are adequate protections with regard to human subjects.
2. The IRB will review amendments and continuing reviews for active studies where COI disclosures are awaiting COI committee review so long as the project team member's disclosure is the same as last year and their study roles remain unchanged.
3. The IRB does not complete its review and approval of the IRB application for a new project or study team amendment until it confirms a disclosure has been submitted, reviewed and receives the final approved management plan or decision memo, if applicable. The IRB reviews the plan/memo as it pertains to the project under IRB review using either the convened IRB or expedited procedures based upon whether the study is eligible for expedited review.
4. The IRB determines whether the stipulations for managing the COI adequately protect the rights and welfare of human subjects or whether additional actions are necessary to minimize the risks to subjects. The IRB determines the kind, amount, and level of detail of information the PI must provide to subjects in the informed consent process regarding source of funding, funding arrangements, financial interests of parties involved in research, and any techniques applied to manage financial COI. Actions required to mitigate actual or perceived conflicts of interest identified or suspected upon initial review of a research protocol proposal will depend on the nature and seriousness of the perceived conflict. Actions the IRB may require to minimize or discharge conflicts of interest may include but are not limited to any of the following:
  - Modification of the protocol procedures or of the roles of specific research team members
  - Independent safety monitoring and/or review of study data and methods of data analysis
  - Divestiture of significant financial interest
  - Reassignment, suspension or termination of specific roles among research team members
  - Withdrawal from all or part of the research project of one or more researcher team members
5. The IRB has the final authority to decide whether the interest and management, if any, allows the research to be approved. The IRB may impose further restrictions on the protocol or disapprove the protocol. The IRB does not have the authority to disapprove the final IO approved management plan but may require additional protections for human subjects before the research can be approved.