



The University of New Mexico

HSC Conflicts of Interest Committee

To: HSC faculty, staff, and students engaged in research

From: HSC Conflicts of Interest Committee

Date: January 8, 2014 (revised: March 17, 2015)

Subject: Guidance document for UNM HSC investigators with outside business interests

The purpose of this memo is to clarify and provide guidance on outside business relationships and conflicts of interest to our faculty and staff. A financial conflict of interest is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.¹ It is the responsibility of UNM HSC investigators to disclose to the university significant financial interests related to their institutional responsibilities.² The university, *not* the investigator, determines the relatedness of financial interests to proposed or ongoing research, whether there is a financial conflict of interest that requires a management plan, and how any management plan will be implemented and overseen. The HSC COI Committee carries out these responsibilities for research conducted at the HSC.

¹ According to 42 CFR Part 50 (Subpart F, §50.603): A *significant financial interest* consists of any of the following interests of the Investigator (and of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- For any publicly traded entity: the value of any remuneration in the preceding 12 months and the value of any equity interest in the entity, when aggregated, exceed \$5,000.... Remuneration includes salary and any payment for services... (e.g., consulting fees, honoraria, paid authorship); equity interest includes stock, stock options, or other ownership interest....;
- For any non-publicly traded entity: the value of any remuneration received from the entity in the twelve months, when aggregated, exceeds \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant financial interest *does not* include:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator ... employed or ... appointed by the Institution;
- Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Income from investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions...;
- Income from seminars, lectures, or teaching engagements, or income from service on advisory committees or review panels sponsored by a Federal, state, or local government agency, an Institution of higher education..., an academic teaching hospital, a medical center, or a research institute ... affiliated with an Institution of higher education....

² The regulations in 42 CFR Part 50, Subpart F and 45 CFR Part 94 do not apply to SBIR / STTR Program Phase 1 applications, but do apply to later SBIR / STTR phases.

Under UNMHSC Policy an investigator has a financial conflict of interest if research conducted at the HSC or under HSC oversight is either sponsored by an entity in which the investigator has a significant financial interest or has the potential to affect the value of an outside financial interest held or directed by that investigator.³ It is the responsibility of investigators to provide sufficient and timely documentation to the HSC COI Committee (e.g., business or consulting agreements with a sponsor or outside entity with an interest in the research; estimates of fair market value of financial interests to the extent their value can be ascertained) for the Committee to determine whether a financial conflict of interest exists and whether or how it can be managed.

“Investigator” in this context is defined any UNMHSC faculty, staff, student, or non-UNM collaborator with responsibilities pertaining to the design, conduct, or reporting of the research. Research sponsorship may be direct (e.g., grant, contract, or subcontract) or indirect (e.g., providing or loaning technology the entity manufactures or licenses free of charge or at a discount to the investigator with the financial interest when such consideration is not available to others who do not have a financial interest in the entity).⁴

Measures that may be incorporated into a conflict of interest management plan include, but are not limited to:⁵

- a. Written disclosure of financial conflicts of interest to all members of the research team and, in research with human subjects, disclosure directly to participants;
- b. Public disclosure of financial conflicts of interest in any presentations or publications related to the research;
- c. Appointment of an independent monitor with the authority to take measures to protect the design, conduct, and reporting of the research against bias due to the financial conflict of interest;
- d. Modification of the research plan;
- e. Change of personnel or of their responsibilities in the research (e.g., requiring independent data and safety monitoring and data analysis);
- f. Disqualification of personnel in all or part(s) of the research (e.g., in research with human subjects disqualifying an investigator from involvement in eligibility determinations, consenting, or determination of adverse events and whether they are reportable);
- g. Reduction or elimination of the financial interest;
- h. Severance of the relationship(s) giving rise to the financial conflict of interest.

³ Under UNM HSC policies (http://hsc.unm.edu/research/coi/docs/COI_Supplemental_Policy_for_HSC_11-15-10.pdf), federal regulations for promoting objectivity in research funded under US PHS mechanisms (42 CFR Part 50, Subpart F, for grants and cooperative agreements; 45 CFR Part 94 for contracts) are applicable to all research conducted at or under the auspices or oversight of the HSC.

⁴ In general, licensing, donation, loan, or sale of technology or intellectual property by the entity should be to the university, not to the investigator. Gifts, equipment loans, or purchase agreements between a sponsor and the HSC must be free of any stipulations as to the scope of work, data disclosure / nondisclosure, or deliverable work product(s). A sponsored research agreement between the sponsor and the HSC is the mechanism whereby such stipulations may be negotiated and agreed to. An investigator should not be directly involved in the negotiation of a sponsored research agreement between the HSC and any sponsor in which the investigator holds a significant financial interest.

⁵ 42 CFR Part 50 (Subpart F, §50.605) Management and reporting of financial conflicts of interest.

The following scenarios are offered as guidance regarding possible management approaches for an investigator (Dr. Y) who holds a significant financial interest in an outside business (Company X) related to Dr. Y's institutional responsibilities.

- Company X wishes to fund research conducted at UNM HSC in Dr. Y's lab or with Dr. Y as an investigator;
- Company X offers to provide Dr. Y's lab with Company X's technology free of charge or at a discount that is not available to other investigators who do not have an interest in Company X;
- Company X receives funding from a sponsor (e.g. federal, foundation / NGO, or a private company) to conduct research some portion of which will be conducted at or subcontracted to UNM HSC.

Under any of the above scenarios, Dr. Y may not participate in negotiations between Company X and UNM related to the gift or licensing of the technology or between Company X and a third party research sponsor. Potential ways these situations might be managed include:

- 1) As long as Dr. Y holds a significant financial interest in Company X, he should not be PI. A faculty member with no financial interest in Company X serves as UNM HSC PI and oversees all aspects of the research conducted at UNM HSC. In research involving human subjects, Dr. Y also should not serve as co-I or an investigator in the research. Dr. Y may serve as a consultant to the research whose consulting role could be limited (e.g., training of lab or study personnel or quality assurance monitoring).
- 2) A faculty member with no financial interest in Company X serves as the UNM HSC PI who oversees all aspects of the research conducted at UNM HSC. Dr. Y may serve as a co-PI, co-investigator or investigator after reducing or eliminating the significant financial interest in Company X (e.g., divesting equity or stock options or relinquishing a position as officer or director). Dr. Y could serve as a paid consultant or scientific advisor to Company X in areas *unrelated* to the research,⁶ provided that aggregate remuneration is reasonable in relation to

⁶ Consulting agreements between a faculty member and an outside entity must not confer any rights to research conducted at the university or involving use of university resources. Consultation involves exchange of ideas, not conducting or collaborating in research on behalf of an outside entity. Research work can, under some circumstances, be agreed to *by the university* as work for hire under a professional services contract or sponsored research agreement.

the services rendered and provided there is no conflict of commitment as defined under UNMHSC policies.⁷

- 3) In the compelling circumstance in which Dr. Y has unique technical expertise such that the scientific merit or safety of the research would be compromised were anyone else to serve as PI, it may be permissible for Dr. Y to serve as PI if another faculty member or oversight committee with no financial interest in Company X is appointed as an independent monitor with the authority to oversee the performance of all aspects of the research, including financial oversight, data collection and analysis, and reporting of the research (to HSC regulatory bodies, to the sponsor, and in any publications or presentations). The monitor(s) cannot be an investigator or consultant in the research activity and preferably should not be in a subordinate or reporting relationship with Dr. Y.

The presumption against a conflicted individual serving as investigator is especially strong for research involving human subjects in which there is greater than minimal risk as determined by the Human Research Protections Office. To rebut that presumption, the investigator must provide the COI committee with a written justification of the compelling circumstance(s) together with a letter from the department chair or Dean supporting that justification. For consideration to be given to allowing the conflicted investigator to serve as PI, the department chair or Dean should also indicate how the resources necessary for implementation and monitoring of an approved management plan will be provided.

Absent a compelling justification rebutting the presumption against a conflicted individual serving as an investigator, the primary COI management options involve either: (a) not serving as an investigator in research sponsored by an entity in which the individual has a significant financial interest; or (b) reducing or eliminating the significant financial interest (e.g., remuneration, equity, or options); or (c) severing the relationship giving rise to the conflict (e.g., resigning a position as officer, director, or board member), in which case serving as an investigator in research sponsored by that entity may be acceptable provided all other HSC policies and COI management plan conditions are satisfied.

⁷ University of New Mexico Health Sciences Center. (2008, last update November 30, 2010). Health Sciences Center Faculty Outside Professional Activities. Retrieved from http://hsc.unm.edu/research/coi/docs/HSC_Faculty_Outside_Activities_Policy_10nov30.pdf In addition, see Faculty Handbook Policy C130: Outside employment and conflicts of commitment (<http://handbook.unm.edu/section-c/c130.html>), according to which: "Employment as a full time, tenured, probationary, or clinician educator faculty member at the University of New Mexico requires an individual's full time professional commitment and expertise." A conflict of commitment exists "when the external professional activities of the faculty member are so extensive and demanding of time and attention as to interfere with the individual's responsibilities to the unit to which the faculty member is assigned by contract, to students, or to the University." Policy C130 expressly prohibits "...consulting or other services to an outside entity when those services would conflict or be in competition with services offered by the University itself."