

**ADDITIONAL CONFLICTS OF INTEREST REPORTING
REQUIREMENTS FOR HSC INVESTIGATORS****Implemented August 24, 2012****Revised 5-26-15**

The federal regulations on Financial Conflicts of Interest (FCOI) were revised on August 2011. The federal regulations can be found at http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf. As a result of this revision to the regulations, UNM HSC has deployed guidelines consistent with NIH requirements and AAMC guidance which are more restrictive than the requirements of UNM Faculty Handbook Policy E110 *Conflicts of Interest in Research*. HSC faculty engaged in research must comply with the additional requirements outlined below which supersede the relevant portions of Policy E110.

1) DEFINITIONS

- a) **Investigator** means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. This will include faculty, staff, students, and all outside collaborators and consultants. Faculty and staff time efforts will include full- and part-time employees, as well as, retired employees (0.25 FTE).

This definition is *not* the same as a **senior/key personnel** which are those individuals identified as such in a grant application, progress report, or any other report submitted to an internal or external funding agency.

- b) **Institutional responsibilities** mean an Investigator's professional responsibilities on behalf of UNM HSC. These responsibilities include but are not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, service on such panels such as the Human Research Review Committee or Data and Safety Monitoring Boards.

- c) A **significant financial interest (SFI)** is defined as:

- i) A financial interest consisting of one or more of the following interests of the Investigator (*and those of the investigator's spouse/domestic partner and dependent children*) that reasonably appears to related to the investigator's institutional responsibilities:

- (1) When the value of any remuneration received from a publicly traded entity in the 12 months preceding the disclosure *and* the value of any equity interest in the entity at the date of disclosure, when aggregated, exceeds \$5,000. A "publicly traded entity" refers to any domestic or foreign, public organization (excluding a Federal agency) that offers its securities (stocks/shares,

bonds/loans, etc) for sale to the general public, typically through a stock exchange or through market makers operating in over-the-counter markets. “Remuneration” includes any salary and any payment for services (e.g. consulting fees, honoraria, paid authorship). “Equity interest” includes any stock, stock option, or other ownership interest.

- (2) When the value of any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated exceeds \$5,000 *or* when the Investigator holds *any* equity interest in non-publicly traded entity.
 - (3) Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests *unless* such rights and interests are from UNM or UNM Science and Technology Corporation (UNM STC).
- ii) Reimbursed or sponsored travel (i.e. paid on behalf of the Investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to institutional responsibilities must be disclosed unless the travel is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, including an academic teaching hospital. Information disclosed includes the purpose of the trip, the identity of the sponsor/organizer, the destination and duration. Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest with the research.
- iii) Participation as a speaker or in another role in a vendor-sponsored event needs to be declared as a potential COI. The COI Committee will make a determination of whether it is a potential COI that needs to be managed or eliminated.
- d) A significant financial interest does *not* include:
- i) Salary, royalties, or other remuneration paid by UNM to the investigator if the investigator is employed or appointed by UNM. This includes intellectual property rights assigned to the UNM or UNM STC and agreements to share in royalties related to such rights.
 - ii) Income from investment vehicles that the Investigator does not directly control the investment decisions made in these vehicles such as mutual funds and pension accounts. Investment vehicles that relate to the study and are controlled by the investigator must be declared (e.g. pharmaceutical company study).
 - iii) Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an Institution of higher education, including academic teaching hospitals.
 - iv) Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, including an academic teaching hospital.

- e) In cases of uncertainty, the investigator should declare an outside relationship for evaluation by the COI Committee.

2) PROCEDURES

a) COI Disclosure Form Submissions

COI disclosure forms are included in all research proposals/protocol submissions to the following offices: UNM HSC PreAward, Human Research Protections Office (HRPO), Research Allocation Committee (RAC), and the Office of Animal Care and Compliance (OACC). OACC COI disclosure submissions occur when a disclosure form was not previously submitted to PreAward and/or the research is nonsponsored.

b) Additional Responsibilities of UNM HSC regarding Financial Conflicts of Interest (FCOI)

- i) UNM HSC is required to provide training to investigators on the UNM conflicts of interest policies, the investigator's responsibilities regarding disclosure of SFIs, and on the federal regulation on FCOI prior to engaging in any research. This is to occur at least every four years and immediately when any of the following occurs:

- (1) UNM HSC revises its COI policies and procedures in any manner that affects the requirements of Investigators;
- (2) An Investigator is new to UNM HSC; or
- (3) UNM HSC finds that an Investigator is not in compliance with the HSC's COI policy or management plan.

- ii) UNM HSC will make available via a written response to any requestor within five business days of a request of information of any significant financial interest disclosed to the UNM HSC that meets criteria set by federal regulation for public disclosure:

- (1) The SFI was disclosed and is still held by the senior/key personnel;
- (2) UNM HSC determines that the SFI is related to the research; and
- (3) UNM HSC determines that the SFI is an FCOI.

The information, at minimum, to be released is the following:

- (1) the investigator's name;
- (2) the investigator's name title and role with respect to the research project;
- (3) the name of the entity in which the SFI is held;
- (4) the nature of the SFI;
- (5) the approximate dollar value of the SFI (permissible ranges are \$0-\$4,999; \$5,000-9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

3) FORMS

The HSC COI disclosure forms are located at:

<http://hsc.unm.edu/research/coi/coiforms.shtml>.