UNM HEALTH SCIENCES CENTER

Applies To: **HSC**
Responsible Department: **Office of Research**
Revised: 3/21/2011

Title: **Institutional Conflict of Interest**				**Policy**	
Patient Age Group:	(X) N/A	( ) All Ages	( ) Newborns	( ) Pediatric	( ) Adult

POLICY STATEMENT

An institutional conflict of interest (institutional COI) describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's activities. The risks are particularly acute in the context of human subjects research, when the protection of human subjects and the integrity of the institution's research may be threatened. The policy is intended to protect against exposure from these risks as they may affect research performed at or under the auspices of the institution.

An institution, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the institution in many forms, including major gifts, royalty payments and equity from licensing intellectual property as well as sponsored educational and research agreements. In addition, university industry relationships are essential to advance scientific frontiers and enable the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the institution's primary missions, including the safety and integrity of its research, education, and clinical care. The protection of human research subjects and integrity of the institution must remain of highest priority.

APPLICABILITY

This policy applies to administrative officials at UNM HSC to include chancellor, vice chancellor, associate vice chancellor, deans, executive vice dean, senior executive financial officer, health system chief operations officer, health system chief clinical affairs officer, executive physician-in-chief, and with respect to the UNM HSC's University Research Park and Economic Development Act Corporations, the chief executive officer, president and chief financial officer, and chief medical officer, associate deans, department chairs, center directors and/or chief executive/operations officers, and chairs of all compliance committees which include the Human Research Review Committee (HRRC) or Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Conflicts of Interest (COI) Committee, Institutional Biosafety Committee (IBC), Radiation Control Committee (RCC), Human Tissue Oversight Committee (HTOC) and Stem Cell Committee.

POLICY AUTHORITY

Chancellor for Health Sciences
Vice Chancellor for Research
HSC Institutional Conflicts of Interest Committee

REFERENCES

Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research, AAMC-AAU Report, February 2008
https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=220&prv_id=268

DEFINITIONS

Institutional Conflict of Interest: An institution may have a conflict of interest ("institutional COI") whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review, or oversight of human subjects research.

PROCEDURE

1. Identification of Potential Institutional Conflicts of Interest

1.1 The following significant financial and fiduciary interests of the institution warrant formal review of potential institutional COI with respect to human subjects research, as provided in this policy.

a) Royalties: institutional COI may be present when the institution has the potential to receive significant milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;

b) Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* company that is i) the sponsor of human subjects research at the institution, or ii) the manufacturer of a product to be studied or tested in human subjects research at or under the auspices of the institution;

c) Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding $100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a *publicly-traded* company that is i) the sponsor of human subjects research at the institution, or ii) the manufacturer of a product to be studied or tested in human subjects research at or under the auspices of the institution.

1.2 The following significant financial and fiduciary interests of covered officials warrant formal review of potential institutional COI with respect to human subjects research. Covered institutional officials are senior administrative officials to which the institutional COI applies. These include but are not limited to the following: chancellor, vice chancellor, associate vice chancellor, deans, executive vice dean, senior executive financial officer, health system chief operations officer, health system chief clinical affairs officer, executive physician-in-chief, and with respect to the UNM HSC's University Research Park and Economic Development Act Corporations, the chief executive officer, president and chief financial officer, and chief medical officer, associate deans, department chairs, center directors and/or chief executive/operations officers, and chairs of all compliance committees which include the Human Research Review Committee (HRRC) or Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Conflicts of Interest (COI) Committee, Institutional Biosafety Committee (IBC), Radiation Control Committee (RCC), Human Tissue Oversight Committee (HTOC) and Stem Cell Committee.

1.3 Institutional Officials: When, with regard to a specific research project to be conducted at or under the auspices of the institution, institutional officials with direct responsibility for human subjects research hold a significant financial interest in the commercial research sponsor or an entity that owns or controls the investigational product. "Significant financial interest" is defined for this purpose as being consistent with the institution's individual conflict of interest policy. In AAMC's guidelines for institutional COI, the definition includes the following:

a) An equity interest or entitlement to equity (including options or warrants) of *any* amount in a *non-publicly traded* company that is i) the sponsor of human subjects research at the institution, or ii) the manufacturer of a product to be studied or tested in human subjects research at or under the auspices of the institution;

b) If the value of any remuneration received from a *non-publicly traded* entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000.
c) If the value of *any* remuneration received from a publically traded entity in the 12 months preceding disclosure and the value of any equity interest in the entity at the date of disclosure, when aggregated, exceeds $5,000.
d) Consulting fees, advisory board fees, remuneration, honoraria, gifts or other emoluments, or "in kind" compensation from a company that is i) the sponsor of human subjects research at the institution or ii) the manufacturer of a product to be studied or tested in human subjects research at or under the auspices of the institution, that in the aggregate exceed the *de minimis* amount (presently $5,000) or are expected to exceed that amount in the next 12 months;
e) An appointment to serve, in either a personal or representative capacity, in a fiduciary role for a company that is i) the sponsor of research at the institution or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the institution, whether or not remuneration is received for such service. Typically, the appointment will involve service as an officer, director, or other board member of the company.
f) An appointment to serve on the scientific advisory board of a commercial sponsor of research conducted by or under the auspices of the institution, unless the official has no current significant financial interest in the sponsor or the investigational product and agrees not to hold such an interest for a period of no less than three years following completion of any related research conducted at or under the auspices of the institution.

1.4 In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant internal or external scrutiny, depending on the circumstances. Examples are listed below. The list is not intended to be exhaustive. In general, institutions should assess the potential for conflict of interest and weigh the magnitude of any risk to human subjects.
a) Individuals responsible for purchasing: When an investigator, research administrator, or institutional official with research oversight authority participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company that sponsors research at the institution, or whose product is being studied or tested in research at the institution.
b) Gifts from sponsors: When the institution has received substantial gifts > $100,000 (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested in research. The following circumstances should be evaluated:
    1. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of research at the institution;
    2. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
    3. Whether any institutional official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

1.5 Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude the institution from accepting philanthropy from companies that sponsor research, or that own or control products that are being studied or tested in research. Rather, the policy is intended to help the institution develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies and reported to the UNM Foundation office for record-keeping purposes. Faculty members are accountable for adhering to institutional gift policies.

2. Administration of Institutional Conflicts of Interest Policy

2.1 The responsibility for institutional COI administration as it relates to research protection is assigned to Vice Chancellor for Research Office, and the reporting structure for the office should be to the Chancellor for Health Sciences who can weigh the needs of the human research subjects protection program in particular and of the institution in general. The office will require access to sensitive data, so appropriate consideration to security must be given.

2.2 To ensure enforcement of the provision that the gifts carry no quid pro quo and tracking of potential institutional COI, administration of institutional COI matters as related to human research protections will be handled by the HSC Office of Research. In order to make the COI Office aware of potential institutional COI situations and transactions as they relate to human subjects research protections, the following offices should report at least quarterly to the COI Office on interests described in Section 3, above:

a) UNM Science and Technology Corporation, UNM STC (for licensing arrangements, patents, invention disclosures);
b) HSC PreAward Office (for sponsored research agreements and products that are the subject of research and state and federal grants);
c) UNM Foundation office (for gifts from private companies);
d) Human Research Protections Office

2.3 Tracking of transactions of the type described in Section1 would be greatly facilitated by the development of one or more comprehensive databases. The Chancellor for Health Sciences will present these reports to the President's office annually.

3. Composition of the Institutional Conflicts of Interest Committee

3.1 The institutional COI Committee will consist of at least four members appointed by the Chancellor for Health Sciences, of whom at least one will be a member of the public with no active transactional relationships with the institution. The public member should have no institutional affiliation at all. In case of the public member affiliated with the institution (for example, alumni), care should be taken that neither they nor their immediate family members are on the institution's payroll. At least two members of the institutional COI Committee should be appointed from the standing individual COI Committee(s). A quorum will consist of three voting members, at least one of whom should be a public member.

3.2 Members of the institutional COI Committee should be free of responsibility for institutional supervision of the human subjects research protection program. They can, however, be principal investigators on human subjects research projects. They should abstain from institutional COI Committee business when they have a personal COI or involvement in institutional COI that relates to a research proposal under review, as provided by institutional policy.

4. Review and Management of Institutional Conflict of Interest

4.1 When a potential institutional COI that involves a human research project is identified, the HSC COI Office will notify the Human Research Protections office and the HSC PreAward office (if the institutional COI involves a sponsored project). The COI Office will review the potential institutional COI and prepare a document describing the case and the nature of the real or potential institutional COI. In cases involving presumptive institutional COI, the case document will be referred to the institutional COI Committee.

4.2 When a potential institutional COI is identified, the institutional COI Committee shall apply a **rebuttable presumption** that either the financial interest should be eliminated or the research should

not be conducted at the institution. The presumption may be rebutted if the circumstances are deemed compelling by the institutional COI Committee, and provided that the Committee approves an effective institutional COI management plan. Whether the presumption is successfully rebutted will depend in each case upon an analysis of:

a) the nature of the science,
b) the nature of the overlapping interests,
c) how closely the interest is related to the research,
d) the degree to which the interest may be affected by the research,
e) the degree of risk that the research poses to human subjects and the integrity of the research, and
f) the degree to which the institutional COI can be effectively managed.

4.3 The Committee should consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved.

4.4 If it is determined that there are compelling circumstances for allowing the research to proceed in the presence of the institutional COI without elimination or significant reduction of the financial interest, those circumstances should be documented in the institutional COI Committee report on the matter. Management plans for approved institutional COI arrangements should be designed effectively to address: 1) the nature of the conflict; 2) the specific risks to human research subjects; 3) the perceived risk to the integrity of the research as a result of the conflict; and 4) the perceived risk to the reputation of the institution.

4.5 One or more of the following management strategies should be used:

a) Disclosure of the institutional COI in the informed consent process;
b) Where the institutional COI involves a senior official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues. (Note that recusal is not an effective management strategy when the individual, by virtue of conflicts arising from personal financial holdings, would be precluded from fulfilling the responsibilities of his or her position. In such cases, the best interests of the institution may necessitate that the individual divest the interests or vacate the position.)
c) Where the institutional COI involves a senior official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator can address institutional COI-related concerns;
d) Use of an external Institutional Review Board (since most institutional IRBs are composed of faculty and staff from the institution);
e) External monitoring of the study, particularly endpoint assessments;
f) Use of an external DSMB or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
g) Disclosure of the institutional COI in public presentations and publications;
h) Disclosure of the institutional COI to other centers in a multi-center trial.

4.6 Approval of management plans will be done initially by school deans (or their designees) or by the senior institutional research officer. The report and the recommended decision should be transmitted to the Chancellor for Health Sciences for final determination, although the final authority rests with the President and HSC Board of Directors. Appeals from initial decisions will follow regular institutional appeal procedures. Review of compliance with management plans will be performed by Institutional COI Committee.

4.7 The COI Office will provide the institutional COI Committee's decision and the underlying report to the Human Research Protections Office and the HSC PreAward Office so that the human subjects review of the project can consider the deliberations and recommended handling of the institutional COI and so that the HSC Office of Research can meet its applicable reporting obligations.

5. Implementation

Each institutional COI management plan should state specifically who will be responsible for the plan's implementation. Adherence to the management plan will be evaluated by the Institutional COI Committee and reported to the HSC Office of Research.

SUMMARY OF CHANGES

Policy placed in UNMHSC Policy Template format on 02/14/2011 (no substantive changes to content).

RESOURCES/TRAINING

Resource/Dept	Contact Information
Conflicts of Interest, HSC Office of Research	272-6433

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	Vice Chancellor for Research		
Consultant(s)			
Committee(s)	HSC Institutional Conflicts of Interest Committee		N/A
Official Approver	Paul B. Roth, MD, Chancellor for Health Sciences		Y
Official Signature	for PBR	03/21/2011	
2nd Approver (Optional)	**Richard S. Larson, MD, PhD. Vice Chancellor for Research**		
Signature		03/21/2011	
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