

**UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
CONFLICT OF INTEREST DISCLOSURE
COVER SHEET**

Name of Principal Investigator Department

Funding Agency Dates of Project

Project Title

The principal investigator must complete and submit this cover sheet with his/her own COI disclosure statement for each proposal or activity that involves research, human subjects, and/or animal subjects, whether the activity is supported by external funding or by an award from an internal UNM source. The principal investigator must also identify each person involved with the project who, by the definition given below, qualifies as an "investigator." It is the principal investigator's responsibility to insure that each "investigator" listed below has been advised of the conflict of interest disclosure policy (see attached). Proposals will not be approved administratively until all "investigators" have properly completed and submitted a COI disclosure statement.

A. Investigators to be paid through UNM as employees:

1.	5.
2.	6.
3.	7.
4.	8.

B. Investigators to be paid through UNM as consultants:

1.	3.
2.	4.

C. Investigators to be paid through Subawards (if the Subcontractor has comparable policies and procedures in place to review and manage potential conflict situations, please attach Subcontractor policy or reference Subcontractor's URL):

1.	3.
2.	4.

D. Investigators not paid by UNM or unpaid investigators (include here UNM faculty, staff, or students who will not be receiving salary support, as well as any unpaid consultants or co-investigators from collaborating institutions):

1.	3.
2.	4.

IMPORTANT: For the purpose of conflict of interest disclosure, an "**investigator**" is the principal investigator, the co-principal investigator, and any person (whether faculty, staff, student, consultant, or collaborator) who is responsible for the design, conduct, or reporting of a UNM research activity that is either supported by external funding or by an award from an internal UNM source. Any individual responsible for a task that could have a significant effect on the design, conduct, or reporting of a project is considered to be an "**investigator**," even if that individual does not have sole or primary responsibility for the task or the activity undertaken.

Sources: For more information on conflict of interest disclosure policy, please refer to the following sources: UNM web address, http://www.unm.edu/~ors/pdf_files/unm_forms/COI_Policy.pdf ; UNM Business Policy and Procedures Manual (UPB) 3715, 3720, 4000 (4.11, 4.12), and 4325 (4); or DHHS/PHS 42 CFR, Part 50.

**UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
CONFLICT OF INTEREST DISCLOSURE STATEMENT**

Investigator's Name ("investigator" as define in the attached policy)

Department

Name of Principal Investigator

Department

Funding Agency

Dates of Project

Project Title

Each investigator must complete this disclosure form and submit it with each proposal for new or renewal support of sponsored UNM research or non-sponsored UNM research that involves human subjects, animal subjects, or research funded by an award from internal UNM sources based on submission of a proposal.

1. Do you (including your spouse, domestic partner, and dependent children) have any of the financial interest(s) described below that are related to the research being proposed? Financial interests are "related to the research" if:

- they are in the sponsor of the research,
- they are in another entity conducting research or business in the same general field as the proposed research (such as a competitor of a drug company or other research sponsor),
- they are in an entity whose interests could be affected by the research (such as a company with ties to the research or whose business might be affected by the outcome of the research), or
- they could be affected by the research (such as where the research outcome might affect the value of stock or the necessity for continued consulting services):

YES NO Aggregated salary, royalties or other payments, such as consulting fees and honoraria, other than through UNM or STC, that are expected to total more than \$10,000 over the next 12 months?

YES NO Equity interests in a single entity, such as stocks, stock options and other ownership interests, that are more than \$10,000?

YES NO Equity interests in a single entity, such as stocks, stock options and other ownership interests, that represent more than a 5% ownership interest?

YES NO Intellectual property rights, such as patents and copyrights, or royalties from these rights, other than through UNM or STC?

2. Do you have any of the following:

YES NO An agreement with one or more private parties that could appear to give them preferential treatment over a government funding agency or other sponsor of the project (e.g. first delivery of project data).

YES NO An agreement to receive financial benefits from the research beyond what is described in the proposal budget submitted to UNM.

YES NO Outside employment that could appear to cause a potential conflict with this research, or raise questions about your professional commitments in undertaking the research or your primary allegiance to UNM.

YES NO A position as a director, officer, partner, trustee, manager or employee of an outside entity that conducts business in an area related to the research.

3. Are you aware of any other potential or actual conflict of interest situations in this research?

YES NO

4. If you have checked YES to any of the above, are you currently under a COI management plan? (leave blank if N/A)

YES NO

FOR CLINICAL TRIALS ONLY

5. Have you been disbarred by the FDA under the provisions of the Generic Drug Enforcement Act of 1992?

YES NO If yes, attach an explanation.

6. Are you currently the subject of a debarment proceeding?

YES NO If yes, attach an explanation.

If I have answered YES to any of the above questions, I have described the situation in detail on a separate sheet and attached it to this form. I know of no other potential or actual conflict of interest situations in this research. I will report any change within 30 days after it occurs.

Signature of Investigator

Date

UNIVERSITY OF NEW MEXICO CONFLICT OF INTEREST IN RESEARCH POLICY

An excerpt of the University of New Mexico Conflicts of Interest in Research Policy, approved by the UNM Board of Regents on April 11, 2000, is shown below. A copy of the full policy is available from the Office of Research Services.

Introduction

Conflicts of interest may occur when an investigator's research responsibilities compete with his or her private interests, such as financial interests, raising questions of objectivity and improper gain. Conflicts of interest are inevitable in modern research universities and do not imply any impropriety on the part of the investigator. A conflict of interest may exist despite the highest standards of conduct and candor. Most conflicts can be successfully resolved without impeding research activities.

Definitions

Conflict of interest means a situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis, that the investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of UNM research activities; or the investigator's situation could directly and significantly compromise his or her professional commitments or allegiance to UNM.

Examples of the types of situations that may come within this definition include:

- Holding a direct or indirect interest in an outside entity that conducts business in an area closely related to the UNM research or serving as a director, officer, partner, trustee, manager or employee in such an entity.
- Undertaking or steering UNM research to serve the research or other needs of an outside entity, without approval of UNM or the research sponsor.
- Directing potential research efforts away from UNM and toward the investigator's outside entity, or an outside entity in which the investigator has a financial interest.
- Transmitting to an outside entity without the sponsor's consent, or otherwise using for personal gain, sponsored work products, results, materials, records or information that are not generally made available. This does not necessarily preclude contracts between faculty start-ups and either UNM or the Science & Technology Corporation@UNM, although these contracts may give rise to conflict of interest situations.
- Using privileged information acquired in connection with the investigator's sponsored UNM research activities for personal gain or for unauthorized purposes. Privileged information includes medical, personnel or security records of individuals, anticipated material requirements or price actions, possible new sites for government operations, and knowledge of forthcoming programs or selection of contractors or subcontractors in advance of official announcements.
- Negotiating or influencing the negotiation of contracts related to the investigator's sponsored UNM research between UNM and outside entities with which the investigator has consulting, equity or fiduciary relationships.
- Accepting gratuities or special favors from entities with which UNM does or may conduct business in connection with sponsored UNM research, or extending gratuities or special favors to employees of the sponsor, under circumstances that reasonably might be interpreted as an attempt to influence the recipients in the conduct of their duties.

PLEASE NOTE: For the purpose of conflict of interest disclosure, an "**investigator**" is the principal investigator, the co-principal investigator, and any person (whether faculty, staff, student, consultant, or collaborator) who is responsible for the design, conduct, or reporting of a UNM research activity that is either supported by external funding or by an award from an internal UNM source. Any individual responsible for a task that could have a significant effect on the design, conduct, or reporting of a project is considered to be an "**investigator**," even if that individual does not have sole or primary responsibility for the task or the activity undertaken.

COI Addendum Form for HSC investigators only

For guidance about conflicts of interest, see the UNM COI policy at: <http://www.unm.edu/~handbook/E110.html> and the HSC COI website at: <http://hsc.unm.edu/research/coi/index.shtml>. The text boxes will expand as you type in your responses.

Part I

Do you (including your spouse, domestic partner, and dependent children), have any of the following interests:

- YES NO 1. Any equity interests (stocks, stock options, or other ownership interests) or derivative financial interests in a non-publicly held outside entity that sponsors the research or when the value of the interest would be affected by the outcome of the research?
- YES NO 2. Any equity interests or derivative financial interests in a publicly held outside entity when the value of the interest would be affected by the outcome of the research?
If YES, name the entity(ies): _____
- YES NO 3. Any compensation from an outside entity when the value of the compensation would be affected by the outcome of the research?
- YES NO 4. A position as a board member or executive officer of an outside entity that sponsors the research or that conducts business in the area related to the research?
- YES NO 5. Any income (regardless of amount) from seminars, lectures, or teaching engagements sponsored by for-profit entities.

Part II

If you answered "Yes" to any questions in the COI disclosure form or in Part I above, please answer the questions below. The text boxes will expand as you type in your response.

1. Identify your role(s) in this research study:

- | | |
|--|---|
| <input type="checkbox"/> Mentoring student research | <input type="checkbox"/> Label/Dispense drug/device |
| <input type="checkbox"/> Design of the study | <input type="checkbox"/> Maintain drug accountability records |
| <input type="checkbox"/> Recruitment of subjects | <input type="checkbox"/> Perform study related procedures (e.g. blood draws, clinic assessments, physical exam) |
| <input type="checkbox"/> Obtaining informed consent | <input type="checkbox"/> Data analysis |
| <input type="checkbox"/> Determining subject eligibility | <input type="checkbox"/> Other (please specify in the text box below): |
| <input type="checkbox"/> Data collection/Data entry | |
| <input type="checkbox"/> Evaluate adverse events | |

2. Provide a description of the financial or other interest endorsed in your disclosure statement or in Part 1 of this form and state whether or not it relates to the current research.

3. Describe measures you plan to take to manage the potential conflict or provide suggestions as to how you might mitigate the conflict.

Certification

In submitting this form, I certify that the above information is true to the best of my knowledge. I know of no other potential or actual conflict of interest situations in this research. I will report any change within 30 days after it occurs.

Instructions: Each PI, Co-PI, and all Researchers that may potentially publish as a result of funding from NIH directly or via a subaward or other funding means must also sign this license and submit with your HSC PreAward proposal.

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Dated: _____

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