

Conflicts of Interest Addendum Form

Marie Barron, M.A.
COI Program Specialist
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Reasons for Addendum

- Investigators often do not explain potential conflict
- Investigator's role not consistently provided
- New HSC Supplemental Policy in effect
- AAHRPP accreditation requirement
- NIH will be changing reporting thresholds
- Not feasible to change original disclosure form

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

Investigator's Name (<i>"investigator" as define in the attached policy</i>)	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

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.

Who Completes Addendum?

- HSC employees/students only
 - Principal & Co-Principal investigators
 - Other investigators
 - Student investigators (fellows, grad, undergrad)
- Investigators with joint appointments
- Non-UNM investigators do not complete

COI form & Addendum

- PreAward Applications:

- <http://hsc.unm.edu/financialservices/preaward/forms.shtml>

- HRRC Applications:

- <http://hsc.unm.edu/som/research/hrrc/forms.shtml>
 - Submission Checklists

- HSC COI Website:

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

Contact Information

Marie Barron, M.A.
COI Program Specialist
abarron@salud.unm.edu
Ph: 272-6433
Fax: 272-0803

Rick Lyons, M.D., Ph.D.
COI Committee C Chair
clyons@salud.unm.edu
Ph: 272-4450