Conflicts of Interest Addendum Form

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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 ("investigator" as defined in the attached policy)

Name of Principal Investigator

Funding Agency

Dates of Project

Department

Department

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 would 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 commitment to 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

Revised December 2005
COI Addendum Form for HSC Investigators only

For guidance about conflicts of interest, see the UNM COI policy at: [https://unm.edu/∼handbook/EL16.htm](https://unm.edu/∼handbook/EL16.htm) and the HSC COI website at: [http://hsco.unm.edu/research/conflicts.htm](http://hsco.unm.edu/research/conflicts.htm). 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?

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 responses.

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

☐ Monitoring student research  ☐ Training students  ☐ Labor/Service of device  ☐ Data collection/Data entry  ☐ Establish study outcomes
☐ Design of the study  ☐ Maintain drug accountability records  ☐ Perform study-related procedures (e.g., blood draws, minor assessments, physical exam)  ☐ Other (please specify in the text box below):

☐ Recruiting of subjects  ☐ Conducting informed consent  ☐ Data analysis  ☐ Other (please specify in the text box below):

☐ Determining subject eligibility  ☐ Evaluate adverse events

2. Provide a description of the financial or other interest endorsed in your disclosure statement or in Part I 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.

Signed: __________________________
Date: 11/03/06
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](http://hsc.unm.edu/financialservices/preaward/forms.shtml)

- **HRRC Applications:**
  - [http://hsc.unm.edu/som/research/hrrc/forms.shtml](http://hsc.unm.edu/som/research/hrrc/forms.shtml)
    - Submission Checklists

- **HSC COI Website:**
  - [http://hsc.unm.edu/research/coi/coiforms.shtml](http://hsc.unm.edu/research/coi/coiforms.shtml)
Contact Information

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