



*Office of the Vice President for Research*

*Conflict of Interest Committee D*

## UNIVERSITY OF NEW MEXICO

### CONFLICT OF INTEREST IN RESEARCH PROCEDURE

Under POLICY: Conflict of Interest in Research, FHB Policy E110

Responsible Executive: Dr. Craig White, Provost

Approving Official: Dr. Gabriel Lopez, Vice President for Research

Effective Date of the Policy: Adopted April 11, 2000;

Revised April 22, 2003;

Approved May 12, 2003.

Date of This Procedure: Adopted June 2012;

Implemented August 2012;

Approved November 2016 & October 2017 &  
December 2018

#### **Procedure Statement and Purpose**

The purpose of this procedure is to define the process for identifying, evaluating, managing, and reporting investigators' relationships that have, or may appear to have, an impact on the objectivity and integrity of research conducted at the University of New Mexico (UNM). This policy applies to research as well as to all sponsored projects. Investigators are required to report: 1) professional outside interests annually and at the time of applying for PHS funds, 2) updates in outside professional and financial interests, and 3) research related interests to enable identification of conflict of interests (COI) in research. This Policy is informed by federal regulations, New Mexico law, and ethical practice regarding the identification and management of COI in research and sponsored projects.

Noncompliance with this policy may result in disciplinary action up to and including termination. UNM supports an environment free from retaliation. Retaliation against anyone who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.



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## Conflicts of Interest

Conflicts of interest exist when financial or other professional interests or considerations of the investigator, or members of his or her immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, an Investigator's professional judgment in exercising any duty or responsibility to UNM, including the design, conduct or reporting of research. Conflicts of interest in research occur when the investigator, or any member of his/her immediate family, possesses a Significant Financial Interest that is in conflict with his or her UNM responsibilities.

Institutional responsibilities:

*“An investigator’s professional responsibilities on behalf of the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs or Data Safety Monitoring Boards”*

Institutional responsibilities for subrecipient investigators only includes the work being done for UNM under the subaward. Only financial and professional interests related to those responsibilities must be reported by subrecipient investigators.

Family Members:

Family member definition includes spouse, domestic partner, and/or dependent children. Most research sponsors and the UNM policy use this definition. However, certain federal agencies may have more expansive definitions.

Senior/key personnel:

Senior/key personnel means the project director and/or principal investigator and any other person identified as Senior/Key Personnel in grant application or any report submitted to a sponsor by or on behalf of UNM.

## FCOI Disclosure Instructions

Overview:

Disclosing the required information at the earliest possible time affords the best protection of an investigator's interests. Investigators are encouraged to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest. Investigators need to err on the side of caution so when in doubt, they should disclose. COI disclosure is required for investigators participating in all research proposals, contracts, & protocol submissions to the following offices:



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- Main Campus Pre-Award Services;
- Main Campus Institutional Review Board (IRB);
- Human Research Review Committee (HRRC);
- Institutional Animal Care and Use Committee (IACUC); or
- Any UNM unit handling internal research awards using a formal review process (RAC, CRTC, ACS-IRG).

**Who should disclose (Investigator definition):**

Disclosure is applicable to all investigators, including faculty, staff, and students. Investigators are defined in the UNM FHB Policy E110, COI in Research, as anyone responsible for a task that could have a significant effect on the design, conduct, or reporting of the research. Any UNM faculty, staff, student, or non-UNM person who is participating in the design, conduct, or reporting of research or a sponsored project that occurs at UNM Main Campus and the Branches and who could influence its design, conduct, or reporting are asked to disclose annually, within 30 days of any material change and, if PHS-supported, to disclose at the time of applying for PHS support.

**What must be disclosed (Significant Financial Interests definition):**

Significant Financial Interests include those of the investigator, his or her spouse or domestic partner, and dependent children. Generally, the following financial interest must be disclosed:

Non-NIH Thresholds:

- More than \$10,000 aggregated in a 12 month period from consulting income and salaries other than through UNM;
- More than 5 % or more than \$10,000 equity in a company;
- Intellectual Property rights such as patents, copyrights and royalties other than through UNM or STC.UNM;
- Other financial interests of value (honoraria, benefits, gifts, equipment);
- Other significant interests include serving as an entity's: Director, Officer, Partner, Trustee, Manager or Employee; or
- Collaboration with family members.

NIH Sponsored Project Thresholds:

- Aggregated salary, royalties or other payments, such as consulting fees and honoraria, other than through UNM or STC, that total more than \$5,000 in a 12 month period;



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- Equity interests in a single entity, such as stocks, stock options and other ownership interests that are more than \$5,000;
- Intellectual Property rights such as patents, copyrights and royalties other than through UNM or STC.UNM;
- Other financial interests of value (honoraria, benefits, gifts, equipment);
- Other significant interests include serving as an entity's: Director, Officer, Partner, Trustee, Manager or Employee;
- Sponsored travel related to your institutional responsibilities from an entity that is NOT a federal, state, or local government agency associated with an institution of higher education; or
- Collaboration with family members.
- Investigators supported by PHS agencies are required to show proof of NIH FCOI training and UNM COI training.

**When a disclosure needs to be made:**

Disclosures should be submitted:

- During the first month of the Fall Academic Year;
- Any time before submitting a proposal to PHS agencies; and/or
- If there is a material change (an acquisition of a significant financial interest or modification to an existing outside interest), the investigator must submit a new disclosure within 30 days of that change.

**Required COI Trainings:**

The PHS/NIH FCOI Training and the UNM COI Training are required for all research personnel at UNM who are responsible for the design, conduct, or reporting of PHS/NIH research projects. The trainings should be completed prior to applying for PHS/NIH funding.

After completion of the PHS/NIH FCOI and UNM COI trainings, please send a copy of the certificate of completion for each training to [coiresearch@unm.edu](mailto:coiresearch@unm.edu). Please also save a copy for your records. These trainings are valid for 4 years and must be renewed thereafter.



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UNM investigators that are not funded by PHS may take the PHS or other COI trainings available on the Research Compliance Web site at: <http://researchcompliance.unm.edu/training>. Regardless of funding, each new research investigator at UNM must complete UNM COI training as part of his/her grants management training prior to beginning research. Non-UNM investigators may take their own institution's COI training.

COI training is to occur at least every four (4) years for PHS-funded investigators and immediately when any of the following occurs:

1. UNM Main Campus revises its COI policies and procedures in any manner that affects the requirements of investigators;
2. An investigator is new to UNM; or
3. UNM Main Campus finds that an investigator is not in compliance with the Main Campus's COI policy or management plan.

### **Disclosure Process:**

The COI annual disclosure information is collected via Opinio electronic survey program which includes encryption to protect information. A call for annual disclosures is deployed every August. The call for disclosures remains open for 1 month. Upon expiration of the deadline to submit annual disclosures, the Research Compliance Office of Conflict of Interest processes survey information, reviews disclosures and prepares disclosures for COI-D Committee's consideration. The Committee meets and deliberates. It may request assistance of the investigator, expert witness, or UNM Office of University Counsel at any time in the proceedings.

Opinio is also used for submittals of Material Change disclosures and PHS-related transactional disclosures (filled out at the time of applying for PHS funds). Regardless of the type of disclosure, the Research Compliance Office of Conflict of Interest reviews disclosures, collects pertinent information, and organizes for the COI-D Committee's reviews.

Investigators who do not disclose COI information which necessitates Committee review are notified that they have fulfilled their annual disclosure obligations and are reminded to disclose any material changes within 30 days of occurrence and to disclose again each time they apply for PHS funding or support.



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Investigators who have disclosed interests that give rise to COI may be asked for additional information and will ultimately be notified of the decision on how to reduce, manage, or eliminate their COI.

Reported financial and non-fiscal interests and research relatedness, if relevant, must be up to date at the time of proposal or protocol submission. Continued updates of outside professional interests and research relatedness are required, as appropriate, for the duration of funding of the research or the life of the IRB or IACUC protocol, whichever is longest.

The COI Office shares information with UNM Office of Sponsored Projects and other research compliance offices to ensure these and the above-discussed training requirements are met by individual investigators. In instances where additional information requested to complete the COI review process is not received in a timely manner, those offices will be notified that the investigator's status is non-compliant with UNM E110. Upon receipt of the needed information and completion of the review process, the "compliant" status will be reinstated and notification sent as appropriate.

### **Public Disclosure:**

The COI disclosure information may be subject to public record requests under laws such as FOIA and IPRA. For details whether an entire disclosure or specific portions thereof may be released in response to public record requests, please see [UNM Public Record Requests web site \[https://publicrecords.unm.edu\]](https://publicrecords.unm.edu) or contact UNM Public Records Custodian at: (505) 277-5035 or [unmipra@salud.unm.edu](mailto:unmipra@salud.unm.edu).

Also, the ORC has to make available, via a written response to any requestor within five (5) business days of a request of information, any Significant Financial Interest disclosed to the UNM Main Campus that meets criteria set by Public Health Service regulation applicable for public disclosure:

1. The Significant Financial Interest (SFI) was disclosed and is still held by the senior/key personnel;
2. UNM Main Campus COI Committee determines that the SFI is related to the research; and
3. UNM Main Campus COI Committee determines that the SFI is a COI

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

1. the investigator's name;



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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.

### **The COI Committee:**

Conflict of Interests Committee (COI-D)

The Conflict of Interests Committee for research is a standing Committee, composed of faculty, administrative personnel, and ex-officio members, as needed, and convened, with an appointed Chair, under the authority of the Provost. The Office of University Counsel (OUC) provides representation to COI-D meetings. The Committee is charged with: 1) evaluating investigator's Significant Financial Interests and other professional outside interests within the context of specific proposals, research and sponsored projects, and research protocols, 2) determining whether outside interests rise to the level of interests that comprise Conflicts of Interest which could directly and significantly affect, or could appear to affect, the design, conduct, or reporting for the research, 3) developing a resolution, including the recommendation of a management plan, as appropriate, and 4) monitoring compliance.

Outside interests are subject to either expedited or full Committee review, based on amount and type of Financial Interests reported. Committee members are required to adhere to applicable rules of privacy and confidentiality when conducting all COI assessments.

Members of the COI-D who have financial or non-financial interests in a particular proposal or IRB or IACUC protocol shall recuse themselves from review of said proposal or protocol.

### **Managing Conflicts of Interest:**

If a Conflict of Interests exists, or appears to exist, that would reasonably appear to compromise the objectivity of the research, the COI-D develops a plan for reducing, managing or eliminating the conflict that must be adopted prior to expenditure by UNM of any part of any sponsored research award or contract and before the research begins. The investigator reporting research-related COI may propose a management plan to the COI-D for ensuring research objectivity that will be considered (but may not be adopted) by the COI-D. Possible management plan components may include, but are not limited to:



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1. Public disclosure of significant financial interests;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in the portion of the funded research that would be affected by significant financial interests;
5. Divestiture of significant financial interests;
6. Severance of relationships that create conflicts; or
7. UNM declining the award.

### **Reporting of and Monitoring the COI Management Plan:**

The financial COI-D's disclosure, determination and/or agreed-upon management plan, if relevant, will be reported to the following, as appropriate:

- The *Office of Sponsored Projects* prior to expenditure by UNM of any part of the affected award.
- The *Office of the IRB* or *IACUC*. The IRB or IACUC may not minimize the management plan developed by the COI-D, but may require additional safeguards to ensure the optimal protection of research subjects. For example, the IRB may require disclosure in the informed consent form or the IACUC may require additional safeguards to protect the well-being of laboratory animals.
- The Department/Division Chair and/or Dean may be notified and asked to participate in development of the management plan, reporting on the management plan, and oversight of the management plan, as needed.
- UNM must inform the PHS sponsor (and prime awardee if UNM is the sub-recipient) prior to the expenditure of research funds, of the existence of any actual conflicts of interest in the funded research and provide assurances of their management in accordance with federal requirements. UNM also must report and handle subsequently arising conflicts in PHS-funded research within 60 days after their identification. UNM is required to report to the National Science Foundation only conflicts of interests that have not been managed prior to expenditure of award funds, and keep the agency informed if a conflict cannot be managed successfully. Office of Sponsored Project reports in accordance with contractual terms or sponsor regulations.





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- The PI directing the research will be notified if he or she is not the conflicted individual. At the request of the COI-D, and as described in the management plan, the investigator must provide an annual, or more frequent, update on the fulfillment of the management plan for review by the COI-D. Non-compliance with the agreed-upon management plan shall be referred to the relevant Dean, Director, or Chair and notification of the IRB, IACUC, and sponsor, as applicable. Sanctions for noncompliance may include removal as an investigator, suspension or termination of the research and/or funding and termination from UNM.

### **Appealing a Conflict of Interests Determination:**

An investigator may appeal a Committee decision to the Provost or designee, who will meet with the investigator and the Committee (or its representative) prior to making a final decision on the appeal. No research expenditures will be made pending appeal.

### **Enforcement and Investigations:**

Under UNM FHB Policy E110, COI in Research, the Provost or designee is charged with enforcement and investigatory responsibilities. If a research Investigator fails to comply with this Policy, s/he may be suspended from all relevant activities until the matter is resolved or other appropriate action is implemented. Sponsoring agency and other research partners may need to be notified of the fact that an investigation has been commenced and, ultimately, the investigation conclusion and findings.

Regardless of funding or its source, failure to comply with the UNM FHB Policy E110 or with a determination under it, will be brought to the attention of the Investigator's supervisor and Dean. Depending upon the egregiousness of the alleged wrongdoing involved, the Provost or the Vice President for Research will have the option of taking appropriate action(s) including, but not limited to, suspension from proposal submittal until the matter is resolved, withdrawal of pending proposals, and/or placing a hold on or terminating an active award, contract, or cooperative agreement. In addition, the University has reporting obligations to the sponsor about any determinations and findings that an Investigator has failed to comply with UNM FHBB Policy E110 on COI in Research.

**Retrospective review.** In situations where COI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose relevant information, or an Investigator's failure to materially comply with a management plan, the Committee will complete a retrospective review of the Investigator's activities and the research project. If the research



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conducted during the period of non-compliance has been biased, the funding agency will be notified and corrective action may be taken to manage the COI going forward or suspensions may occur. If bias by the investigator is found, the report will include a mitigation report in accordance with the applicable regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

### **Records Retention:**

Records of conflict of interest disclosures and all actions taken with respect to those disclosures shall be kept for at least three years after the later of these events:

1. Termination or completion (the date the final expenditures report is submitted) of the UNM research;
2. Resolution of any government action involving the records; or
3. As otherwise provided by law.

Contacts:

The Office of the Vice President for Research officially interprets UNM FHB Policy E110, Conflict of Interest in Research. The Office of the Vice President for Research is responsible for obtaining approval for any revisions to it as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Compliance with UNM FHB Policy E110 is the responsibility of the Provost or designee.

For additional information, please visit: <http://researchcompliance.unm.edu/coi-overview> or call (505) 277-1045 or (505) 277-5358.