

UNIVERSITY OF NEW MEXICO

CONFLICT OF INTEREST IN RESEARCH OPERATING PROCEDURE

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

Responsible Executive: Dr. James P. Holloway, Provost

Approving Official: Dr. Ellen R. Fisher, Vice President for Research

Date of This Procedure: Adopted June 2012; Revised July 2024

Procedure Statement and Purpose

The purpose of this procedure is to describe 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's (UNM) main and branch campuses under Faculty Handbook Policy E110: Conflicts of Interest in Research. This procedure applies to research as well as to all sponsored projects. This procedure is informed by federal regulations, New Mexico law, and ethical practices regarding the identification and management of conflicts of interest (COI) in research and sponsored projects. The Office of Research Integrity and Compliance (ORIC) oversees this procedure.

COI Disclosure Procedure

Disclosing the required information at the earliest possible time affords the best protection of an investigator's interests and the integrity of their research. Investigators are encouraged to disclose any situation that could conceivably be viewed as a COI, conflict of commitment (COC) 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 research proposals, awards, contracts, & protocol submissions to the following offices:

- Main Campus Office of Sponsored Projects (OSP);
- Main Campus Institutional Review Board (IRB);
- Any UNM unit handling internal research awards using a formal review process (e.g., RAC).

Who should disclose (investigator definition):

Disclosures must be submitted by all investigators, including faculty, staff, and students. An investigator is defined in the UNM FHB Policy E110 as anyone responsible for a task that could have a significant effect on the design, conduct, or reporting of UNM research. Any UNM faculty, staff, student, or non-UNM person who is participating in the design, conduct, or reporting of UNM research or sponsored project and who could influence its design, conduct, or reporting are required to disclose annually, and as described in Section 2 of FHB E110.

Content and Timing of Disclosures

Significant financial and non-financial interests of the investigator, his or her spouse or domestic partner, and dependent children must be disclosed. This includes:

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

- Equity interests in a single entity, such as stocks, stock options and other ownership interests that total more than \$5,000;
- Intellectual Property rights such as patents, copyrights and royalties other than through UNM or UNM Rainforest Innovations;
- Other financial interests of value (honoraria, benefits, gifts, equipment);
- Other significant interests include serving as an entity's Director, Officer, Partner, Trustee, Board Member, Manager or Employee;
- Sponsored travel related to an investigator's institutional responsibilities from an entity that is NOT a federal, state, or local government agency associated with an institution of higher education;
- Research collaboration with family members (spouse/partner, dependent children); or
- Participation in a foreign talent recruitment program (see FHB Policy E130).

Disclosures by main and branch campus investigators should be made:

- When the call for annual disclosures is released (fall semester);
- Upon submission of a research proposal to any funding agency;
- Upon submission of a human research protocol to the UNM Institutional Review Board (IRB);
- Within 30 days of acquiring any new reportable interest and/or a change/modification to the investigator's existing COI occurs.
- Immediately, when
 - o UNM revises its COI policies and procedures, as appropriate;
 - o An investigator is new to UNM;
 - o An investigator is not in compliance with UNM's COI policy and/or management plan.

Required COI Training

Investigators must complete COI Training in Learning Central every 4 years; training may also be required when certain revisions to policy are made or when an investigator is found to be out of compliance with UNM policy and/or this procedure.

Disclosure Process

Annually, disclosure information is collected via UNM's electronic Research Administration (eRA) system. A call for annual disclosures is deployed every fall (~September). The call for disclosures remains open for one month. After one month, lists of investigators who failed to submit annual disclosures will be provided to relevant Associate Deans for Research (ADRs). Failure to submit an annual disclosure may preclude the Principal Investigator from spending on new or renewed awards. Other disclosures should be submitted as noted above.

The COI in Research office staff process disclosures as they are received and prepare certain disclosures for the COI Committee's consideration. Low risk disclosures are reviewed administratively.

Investigators who disclose no interests are notified that they have fulfilled their annual disclosure obligations. Investigators who have disclosed interests that give rise to potential COI may be asked for additional information and will ultimately be notified of the COI Committee's decision on how to reduce, manage, or eliminate the COI.

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

The COI Office shares information with OSP 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 is non-compliant with UNM E110. Upon receipt of the needed information and completion of the review process, compliant status will be reinstated, and notification sent as appropriate.

UNM Conflict of Interest Committee

The COI Committee for research is a standing committee with an appointed Chair, composed of main campus faculty, administrative personnel, ex-officio members and others, as needed, convened under the authority of the Provost. The Committee meets monthly, or as needed. It may request assistance of the investigator, expert witness, or Office of University Counsel at any time. The Committee is charged with: 1) evaluating investigators' significant financial interests and other professional outside interests within the context of specific proposals, sponsored projects, and research protocols; 2) determining whether outside interests rise to the level of interests that comprise one or more conflicts of interest that 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.

Committee members are required to adhere to applicable rules of privacy and confidentiality when conducting all COI committee business. Members of the committee who have financial or non-financial interests in a proposal or IRB protocol or are unable to be objective shall recuse themselves from review of said proposal or protocol.

Managing Conflicts of Interest

If a COI exists, or appears to exist, that would reasonably appear to compromise the objectivity of the research, the committee 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. Possible management plan components may include, but are not limited to:

1. Public disclosure of significant financial interests;
2. Monitoring of research by independent reviewers (such as the immediate supervisor or someone higher in the reporting structure);
3. Modification of the research plan;
4. Changing the supervisory status of the PI over students, postdoctoral researchers, or other staff;
5. Disqualification from participation in the portion of the funded research that would be affected by significant financial interests;
6. Divestiture of significant financial interests;
7. Severance of relationships that create conflicts; and/or
8. UNM declining the award.

Both the investigator and appointed monitor (if applicable) must sign and return the plan to the COI Office before the conflict is considered managed. The investigator and monitor are expected to meet at least once annually to review the plan and discuss conflict management. Additional meetings should be held if significant changes to the COI disclosure occur.

COI Reporting and Public Disclosure

The COI disclosure, determination and/or management plan, if relevant, may be reported to the following, as appropriate:

- The *Office of Sponsored Projects* will ensure that any COIs have been managed prior to expenditure by UNM of any part of the affected award.
- The *UNM IRB* may require additional safeguards, above those required in the management plan, to ensure the optimal protection of research participants. For example, the IRB may require disclosure in the informed consent form.
- The *Department/Division Chair and/or Dean* may be notified and asked to participate in development of and reporting on the management plan, and/or may be asked to serve as COI monitor in the management plan, as determined by the COI Committee.
- UNM must inform any *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 only required to report COIs that have not been managed prior to expenditure of award funds to the National Science Foundation (NSF), and keep the agency informed if a conflict cannot be managed successfully. OSP reports in accordance with contractual terms or sponsor regulations.
- At the request of the COI Committee, 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 office. Non-compliance with the agreed-upon management plan shall be referred to the relevant Dean, Director, or Chair and notification of the IRB 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.

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.

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

1. The 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 minimum information to be released is the following:

1. the investigator's name, title, and role with respect to the research project;
2. the name of the entity in which the SFI is held;
3. the nature of the SFI;
4. 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.

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 COI Committee will conduct a retrospective review of the investigator's activities and the research project(s). If the research conducted during the period of non-compliance has been biased, the funding agency and the Provost 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 COI 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

ORIC under the Office of the Vice President for Research (OVPR) officially interprets UNM FHB Policy E110, Conflict of Interest in Research.

For additional information, please visit: <https://researchcompliance.unm.edu/conflict-of-interest/index.html> or call (505) 277-1045 or (505) 277-5358.