THE UNIVERSITY of NEW MEXICO



UNM Conflict of Interest (COI) Training

Office of Research Integrity & Compliance

https://researchcompliance.unm.edu/

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What is a Conflict of Interest?

A situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis:

- 1. that the investigator's significant financial interest could directly and significantly **affect the design**, **conduct or reporting** of UNM research activities; or
- 2. the investigator's situation could directly and significantly compromise his or her professional commitments or allegiance to UNM.



Examples of Potential Conflicts of Interest (COI)

- » A research investigator's consulting relationship outside of UNM in the areas of his/her research.
- » A role or equity/financial interest in an outside entity that conducts activity in an area related to investigator's UNM research.
- » Ownership in patents or technology, other than through UNM.STC.
- » Creating a start-up company based on technology associated with UNM research.
- » Supervising the same student(s) both in a UNM activity and as employees of outside entity.
- » Steering research activity away from UNM.
- » Accepting or giving gratuities/special favors that may influence the recipient/s in the conduct of their duties.

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Examples of Managing Potential COI

- Public disclosure of the conflict.
- Monitoring of the research by independent reviewers and imposition of a management plan.
- Modification of the research plan.
- Divestiture of the investigator's conflicting financial interests or placement in a blind trust.
- Escrow of an equity interest until certain triggering conditions are met.
- Prohibition on the investigator's involvement in contract negotiations for the research.
- Severance of the investigator's relationships that create the conflict.
- Disqualification of the investigator from participation in part of the research.

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Examples of Different Levels of Conflicts

» COI that is inherent in academic activity:

- Book and publication royalties in an area of the research investigator's expertise.
 - [This type of COI typically does not result in any management recommendation beyond potentially public disclosure.]

» COI that can impact UNM research but can be managed:

Affiliation or activity outside UNM which, with proper monitoring and management, will not adversely impact integrity of UNM research.

[This type of COI usually results in a management stipulation and/or a management plan.]

» Unmanageable COI:

- Control or influence over the integrity of UNM research or its results by anyone other than researchers engaged in and retained for the purpose of performing UNM research. Even sponsors and donors who are engaged through UNM and UNM Foundation cannot control or influence the integrity of UNM research or its results.
- [If an arrangement cannot be devoid of such control or influence, the research investigator will be asked to divest him/herself of the outside affiliation or interest, his/her UNM role, or his/her role in UNM research.]





UNM Policy E110: Conflict of Interest in Research

UNM's policy E110 on Conflict of Interest in Research is to protect the integrity, trust and respect of UNM, its academic community and its research activities. The policy complies with federal regulations and applies to all UNM faculty, staff and students, including non-UNM research investigators.



Goals of UNM COI Policy E110

Conflicts of interest are inevitable in modern research universities and do not imply any impropriety on the part of the research investigator. A conflict of interest may exist despite the highest standards of conduct and candor.

Conflicts of interest frequently involve perceptions, and are judged by others not necessarily directly involved. When in doubt, erring on the side of disclosure is encouraged. Disclosure does not automatically mean a conflict- this is what the Committee will decide.

While it is not possible to **eliminate** all conflict, the goal is to **manage** any potential conflict and the key is:



DISCLOSURE



COI Disclosure

The UNM COI disclosure form is a confidential disclosure of investigator's interests as related to his/her research.

Interests are **"related to the research"** if an investigator has a relationship with an entity outside of UNM that has either an interest in the subject matter of an investigator's research or whose activities overlap with an investigator's area of expertise or UNM research.

UNM research means a systematic investigation designed to develop or contribute to generalizable knowledge, including basic and applied investigations and product development, that is:

- 1. Funded by or through UNM (including outside sponsored funding);
- 2. Conducted at UNM, regardless of funding; or
- 3. Non-sponsored and conducted off campus by UNM employees.



Disclosure requirements apply to all investigators involved in:

- > Any Sponsored UNM Research
- ➤ Any Non-sponsored UNM research that is:
 - Human Subject Research;
 - Animal Subject Research; or
 - Research funded by a formal award from internal UNM sources based on submission of a proposal (such as RAC/ WeR1 SuRF awards).





Who must disclose?

Any individual responsible for a task that could have a significant effect on the research design, conduct or reporting is considered to be an investigator, even if the individual does not have sole or primary responsibility for the task or the research.

- Principal investigator
- Co-principal investigator
- Faculty, staff and students
- Non-UNM Consultants or Team Members



What must be disclosed?

- Financial interests of the investigator, his or her spouse or domestic partner, and dependent children.
 - •More than \$10,000 in consulting income, salaries, royalties, payments such as honoraria or equity. Interests and ownership.
 - •More than 5% equity in a company.
- Intellectual Property rights and royalties other than through than UNM.STC.
- Outside employment that could appear as a potential conflict.
- Position as a director, officer, partner, trustee, manager, or employee of an outside entity that conducts business in an area related to UNM research.
- Married couples or domestic partners or immediate family members collaborating on UNM research.
- Any other situation that could call into question the investigator's professional commitments in undertaking UNM research or the investigator's primary allegiance to UNM.



PHS (NIH)- and DOE- specific Thresholds:

- ➤ Salaries, royalties or other payments, such as consulting fees and honoraria, other than through UNM or STC.UNM, that exceed \$5,000 during the 12 months preceding disclosure, when aggregated for the investigator, spouse, and dependent children.
- ➤ Equity interests in a single entity, such as stocks, stock options and other ownership interests.
- > Sponsored travel related to your institutional responsibilities from an entity that is NOT a federal, state, or local government agency or associated with an institution of higher education.

A separate NIH FCOI training is mandatory for investigators involved with research funded by PHS (includes NIH). The NIH FCOI training is found at:

https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

When engaged in PHS (NIH) research, your NIH FCOI training must be renewed every 4 years (as does the UNM COI training).



Disclosure Submission

Annual COI disclosures are required from all investigators engaged in UNM research at Main and Branch campuses. A call for annual submissions occurs every August. However, investigators are able to submit an annual disclosure at any time during the academic year.

Public Health Service (PHS) disclosures are required for each PHS proposal submitted. Submission is needed prior to the time of every new proposal submission to any PHS agency, including NIH and NIH-affiliated agencies and institutes.

Department of Energy (DOE) disclosures are required for each DOE proposal submitted. Submission is needed prior to the time of every new proposal submission to any DOE funder, including national labs

Material Change disclosures are submitted when there is a material change, such as, a new significant financial interest; a new situation that could call into question or impact professional commitments or primary allegiance to UNM; or a significant change to a previously submitted disclosure.



How do I disclose?

- Disclosures are submitted via Office of Research & Compliance's electronic COI disclosure system.
- Links to disclosures are on the web page:
- https://researchcompliance.unm.edu/conflict-ofinterest/submit-a-disclosure.html



The Review Process

Each disclosure will receive an initial review and you will be notified of that determination. If the disclosure requires a review by the full COI Committee, you will be notified of their decision via email. You could be asked to be present at the Committee meeting.

To assist and to speed up the review process, it is essential that the investigator provide detail in the information given in the disclosure. The COI Committee conducts the review process in a manner that is intended to foster, not hinder research relationships.





Key UNM COI Policies:

The principal policy addressing Conflict of Interest in Research is

UNM FHB E110

Other Key Policies

- UNM Faculty Handbook E80: Conflict of Interest Waiver Policy for Technology Transfer
- COI in Research Procedure under UNM Policy E80
- UNM Faculty Handbook C130: Outside Employment and Conflicts of Commitment
- Administrative Policies and Procedures Manual Policy 3720: Employee Code of Conduct and Conflicts of Interest
- <u>Regents' Policy Manual Section 5.10: Conflicts of Interest in Research</u>
- Regents' Policy Manual Section 5.17: Conflict of Interest Waiver Policy for Technology

 Transfer





Related UNM Policies:

Related Policies

• <u>UNM Faculty Handbook E70: Intellectual Property Policy</u>

• Regents' Policy Manual - Section 3.4: Health Sciences
Center and Services



Contact Information

(right click to open hyperlinks)

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COI in Research webpage:

https://researchcompliance.unm.edu/coi-overview



Thank you for taking UNM's Conflict of Interest training.

This training will have to be renewed every 4 years.

Certificate of Completion

Name:

Email:

Date Completed:

(When filled in, print this slide as a pdf and email document to coiresearch@unm.edu)

For the separate NIH FCOI training, go to:

https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

(right click to open)