

# Brief Monitor Training

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3 August 2023

# Federal Regulations Require

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That information regarding real or potential conflicts of interest be collected at least annually.



That these conflicts be reviewed and the risk of the conflict assessed.



That any identified conflicts be managed:

Elimination of the conflict

Removal of the conflicted researcher from the project

Managing the conflict.

# Who needs to complete a disclosure?

Principle Investigators, co-PIs, key personnel and anyone who can affect the “design, conduct, or reporting” of UNM research.

- **Design of Research** means the planning of the strategy to conduct the research/project.
- **Conduct of Research** means the supervision or management of a study’s execution. This can include the principle investigator or co-investigator, but may also be performed by postdoctoral fellows and graduate students who have significant supervisory roles over junior researchers or technicians who are part of the project.
- **Reporting of Research** means the authorship of publications to journals or otherwise, reports to the research sponsor, or presentation at conferences or scientific meetings related to the research.

UNM research:

Research and projects funded by or through UNM (including outside sponsored funding).

Research conducted at UNM, regardless of funding.

Un-sponsored UNM-affiliated research conducted off campus by UNM employees.

# What sorts of information needs to be disclosed

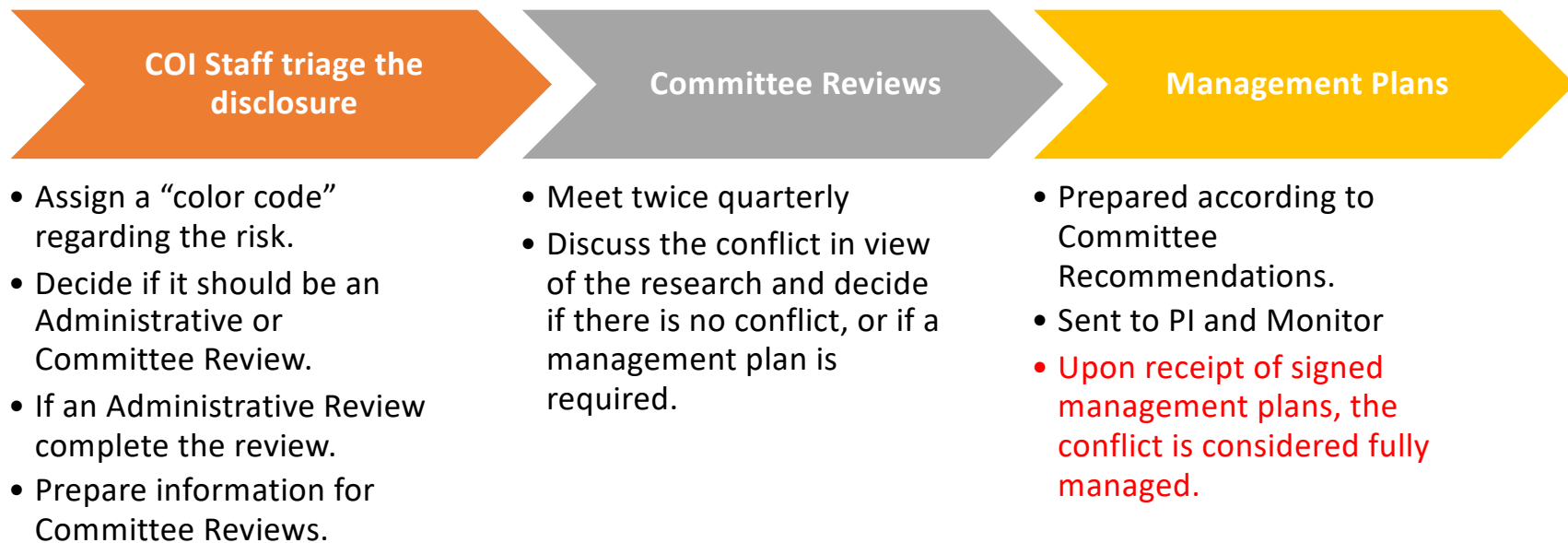
## Financial Conflicts of Interest:

- Ownership interests in for profit companies.
- Remuneration from outside of UNM.
- Certain stock and stock option ownership.
- Non-UNM intellectual property.

## Non-financial Conflicts of Interest

- Non-financial support to the research program.
- Indirect support.
- Foreign collaborations.
- Family collaborations.
- Executive positions or service on certain boards of directors, especially if the entity does business with UNM.

# What is the process after the we receive an affirmative disclosure



# UNM Faculty Handbook E110 directs how UNM has chosen to manage the conflict

## “D. Management of Conflicts of Interest

1. If the Conflicts of Interest Committee determines that an investigator has a conflict of interest in UNM research, it will decide how the conflict should be managed so the research may proceed if at all possible. The Committee may impose conditions or restrictions to control, reduce or eliminate the possibility that the conflict will affect the objectivity of the research. The Committee may designate other UNM officials to assist in this process. Examples of conflict of interest management options include:

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

2. All conflicts of interest must be managed to the satisfaction of the Committee for the UNM research to proceed and for funding, if any, to be accepted. This applies to all UNM research that is subject to the disclosure requirements of this policy, regardless of whether the research is funded. No conflicts may be waived. **If a conflict of interest cannot be managed, the investigator must withdraw from the research and UNM may need to decline acceptance of the award or terminate the sponsored agreement.”**

# The COI committee

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Is composed of 10 people

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Includes faculty, administrative staff, and community members.

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Is supported by COI program staff.

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Have all signed confidentiality agreements.

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Will recuse themselves from projects in which they are involved or have a close affiliation with the respondent.

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Must have a quorum to meet and decisions are made by majority rule.

# How monitors are decided by the COI Committee

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Must have a supervisory position over the person being monitored

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Department Chair or Center Director

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Associate Dean for Research

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Dean

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Associate Dean for research of an affiliated department

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Vice President for Research

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Provost

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# How do we monitor people- the Management Plan.

States the real/potential conflict(s) of interest as determined by the COI Committee.

Provides stipulations for managing the conflict

Appoints a monitor



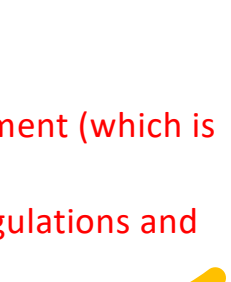
The Committee requests that you comply with the following:

1. Regular consultation with and oversight [REDACTED] on matters regarding research activity where collaboration with [REDACTED] is involved.
2. For projects where you are collaborating with your spouse, discuss methodology, data analysis, and interpretation with the Plan Monitor to ensure integrity of research.
3. The Committee would like to remind you that all grants require one identified PI with final authority; others listed as co-PIs are indeed under the supervision of PI, in some substantial sense. While your research roles on the project may be equal, there is a structural relation regarding authority that all need to be clear about (and perhaps rotate in, on different grants). For the purposes of disclosure of supervisory roles, if one is the PI or otherwise has legal, fiscal, intellectual, or other organizational authority formally constituted, then there is a supervisory relationship involved. Please note that this designation of “supervisory capacity” applies only to your research roles and will not be interpreted as a violation of either UAP 3210 section 5.11 or FHB C-30 regarding family hires.
4. Disclosure of the spousal relationship to PIs and team members on projects where you and Dr. [REDACTED] collaborate.



Specific activities of [REDACTED] will include the following:

1. Ensure compliance with the aforementioned stipulations of this management plan.
2. Discuss with [REDACTED] matters regarding research collaboration on UNM projects which involve her spouse and provide input and guidance regarding potential conflict of interest issues.
3. Submit a monitor report annually or more frequently if requested by the Committee.

- Usually requires two meetings with investigator a year
    - One to discuss management plan.
    - One to complete the monitor report.
  - Helps you manage potential conflict of commitment (which is not addressed by COI in researcher disclosure).
  - Keeps researcher in compliance with federal regulations and UNM policy.
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# Monitor report

**COI Management Plan Monitor Report**  
2022-2023 COI Disclosure Year

Date

The annual Monitor Report is needed for the COI Management Plan for the individual listed below. Please provide the requested information.

**Management plan for:** Investigator Name, Position Title, Dept  
**Plan Monitor:** Monitor Name, Position Title, Dept

**Investigator Name** disclosed **description of disclosed interest**. The Committee determined that there was a potential conflict of interest between the disclosed interest(s) and the UNM research.

**The stipulations of the management plan to be addressed are:**

The Committee requests that you [Investigator Name] comply with the following:

Copy paste stipulations of the management plan (both Investigator portion and Monitor portion).

**Please describe all actions taken in monitoring each stipulation of the management plan in the space provided on the following page.** If no management is/was needed, please provide a justification (e.g., "individual does not conduct research sponsored by, or of commercial interest to the company" or "individual makes no purchasing decisions regarding the company's products").

The completed report is due by **DATE**, and should be emailed to [coiresearch@unm.edu](mailto:coiresearch@unm.edu).

Thank you,  
Yvonne Marrero  
Office of Research Integrity & Compliance  
(505) 277-5358

Word Document

Yvonne completes

Monitor completes

Questions?  
Discussion?

