CONFLICT OF INTEREST AND COMMITMENT POLICY

Purpose

Active participation by New Mexico Consortium (NMC) employees (full- or part-time) in outside activities that enhance their professional skills or constitute public service can be beneficial to NMC as well as to the individual and is encouraged. The NMC, however, requires that employees remain alert to the possible effect of outside activities on the integrity of their decisions and their ability to fulfill their obligations to NMC. The purpose of this policy is to establish a general framework against which the propriety and advisability of non-NMC activities can be measured and monitored.

Definitions

A conflict of commitment arises when the outside activities of an employee are so demanding of time or attention that they interfere with the individual's responsibilities to NMC.

Outside Activity means any activity that is conducted by an employee for an entity other than NMC and that is not part of the employee's duties assigned by NMC.

A (financial) conflict of interest, (F)COI, occurs when the employee is in a position to advance one's own interests or that of one's family or others, to the detriment of NMC.

In this policy, *CEO* refers exclusively to the Chief Executive Officer of the NMC, and *COO* refers exclusively to the Chief Operating Officer of the NMC.

In this policy, '*Partner Institutions*' refers to Los Alamos National Laboratory, University of New Mexico, New Mexico Institute of Mining and Technology, and New Mexico State University.

In this policy, *'Significant Financial Interest' (SFI)* means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria) exceeding $5,000 per year; equity interest (e.g., stocks, stock options or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights); and ownership representing the lesser of $10,000 or 10% of the equity in the outside organization.

The term 'Significant Financial Interest' does not include:

a. salary, royalties, or other remuneration from NMC;

b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
c. income from service on advisory committees or review panels for public or nonprofit entities;
d. income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions made in these vehicles;
e. an equity interest that, when aggregated for the employee and the employee's spouse and dependent children, meets both of the following tests: (i) does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or
f. salary, royalties, or other payments that, when aggregated for the employee and the employee's spouse and dependent children, are not expected to exceed $10,000 during the prior twelve-month period.

Policy

It is the policy of NMC that employees have an obligation to avoid unacceptable ethical, legal, financial, or other conflicts of interest. It is also the policy of NMC to ensure that employees' outside activities and interest do not conflict with their obligations to the NMC or to the welfare of the NMC and its sponsors. No employee will act in such a way as to compromise these obligations. No employee may use any NMC resources to advance their personal gain, or the gain of others with whom they are related in any manner, via family or contractual obligations, without written permission of the CEO. Furthermore, no NMC employee will conduct business through the NMC in any way with any company in which he/she has Significant Financial Interest or other conflict of interest or commitment without prior written permission of the CEO.

It is the policy of NMC that employees planning to engage in an outside activity must disclose this possibility by requesting NMC to review potential agreements between NMC employees and external institutions before the agreements are signed by the employees. Employees must request the review by sending an email or a signed Conflict of Interest form to hr@newmexicoconsortium.org with an attached copy of the agreement.

It is the policy of NMC that employees possessing a personal interest that could lead to a significant conflict of interest or commitment must immediately disclose that possibility by filing a disclosure form with the HR.

Employees not engaged in outside activities or possessing conflicting interests need only to affirm this fact on the disclosure form when it is required.

NMC employees are encouraged to disclose whenever they are in doubt about the possibility that a conflict of interest may exist. This protects both the NMC and employee against possible future adverse repercussions.

If the CEO, having been provided with all pertinent information, determines that the individual's situation presents a significant conflict of interest or commitment, that situation must be resolved in accordance with this policy.

Additional Requirements for Participants in Sponsored Research

A. All Sponsored Research Projects. Researchers who plan to apply for funding must provide all required financial disclosures for all participants in the proposal **at the time the proposal is submitted** to the sponsor. The original disclosures must be updated during the period of the award as new reportable significant financial interests are obtained.

The NMC will inform the sponsoring federal agency of any COI that have not been managed prior to expenditure of award funds and keep the agency informed if a conflict cannot be managed successfully.

B. Awards Sponsored by Public Health Service (PHS) Agencies. The U.S. Public Health Service (PHS) Health and Human Services (HHS) regulation requires **additional financial disclosure and training** for each investigator who will participate in research funded under PHS grants or cooperative agreements. The term "investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of PHS-funded research or proposals for such funding.

The responsibilities of a PHS-funded investigator include:

- Becoming familiar with the PHS regulations and the NMC's COI policies.
- Completing COI training prior to starting the expenditure of funding and, thereafter, at the required intervals, at least once every four years.
- Disclosing SFIs to the NMC no later than at the time of applying for PHS funding.
- Updating the disclosure prior to starting expenditure of grant funds and at least annually during the period covered by the grant, or within 30 days of identifying or acquiring a new SFI.

- Complying with any management plan issued by the institution and retaining documentation that demonstrates compliance.

The NMC must inform the PHS, prior to the expenditure of research funds, of the existence of any actual conflicts of interest in the funded research, and it must provide assurances of their management in accordance with federal requirements. The NMC also must report and handle subsequently arising conflicts in PHS-funded research within 60 days after their identification.

If an FCOI determination is made, prior to the expenditure of any research funds, the NMC is required to develop and implement a management plan to reduce or eliminate the FCOI, and ensure, to the extent possible, that the research will be free from bias. Common management plan elements include:

- Public disclosure of the conflict of interest in publications and presentations.
- Disclosure to human subjects participating in the research.
- Informing other research team members.
- Appointment of an independent third party to monitor the research.
- Changing personnel or personnel roles in the research.

The investigator is required to confirm agreement with the NMC's management plan, and the NMC is required to monitor the investigator's ongoing compliance with the management plan on an annual basis during the period of the research award. Therefore, it is the responsibility of the investigator to verify compliance by retaining documents such as notices to journal editors or conference audiences, consent forms from human subjects research, or notices to research personnel.

If your research or employment is funded by a PHS agency (e.g., NIH, CDC, etc.), this regulation will affect you. Training and disclosure are required. Links to the list of PHS agencies, training portal, and PHS FCOI form can be found at https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html.

Disclosure

Initial Disclosure.
HR Administrator will solicit initial COI statements or disclosures from new employees during the hiring process.

Research Administrator will solicit initial COI statements or disclosures from

- participants (including NMC employees, joint appointees, and affiliated researchers) in research proposals at the time of proposal submission;
- participants of sponsored research projects prior to expenditure of funding.

Disclosure of outside activities is the responsibility of employees planning to engage in such activities.

Ongoing Disclosure Responsibility
Disclosure requirements apply for the duration of employment with the NMC. Employees must disclose any of the following, among other things, that occur during their term of employment at NMC:

a. A new SFI that would reasonably appear to affect the NMC activity.
b. A new SFI in an entity whose financial interests would reasonably appear to affect the NMC activity.
c. A new situation that could call into question the employee's professional commitments or primary allegiance to NMC.
d. A significant change to a previously reported disclosure.

Research Administrator will solicit disclosures from participants of PHS-sponsored projects annually.

Examples of allowable income-generating activities.
The following are offered as examples of outside, income-generating activities that are not considered conflicts of interest. They are exempt from reporting requirements unless they are so extensive in time and effort that they constitute a potential conflict of commitment.

a. Receiving honoraria, stipends, and/or royalties for published scholarly works and other writing, creative works, lectures, and/or presentations less than $5,000 per year from a single entity.
b. Participating in professional conferences for the purpose of making scholarly presentations, conducting seminars or workshops.
c. Receiving honoraria for serving as a special reviewer or on a review panel for academic, governmental, or not-for-profit organizations.
d. Receiving royalties under the NMC's or another academic institution's royalty distribution policies.
e. Preparing books, articles, software, and creative works relevant to NMC duties.
f. Earning income from passive investments such as interest or dividends from banks, mutual funds, or stocks and bonds.
g. Any work performed for or benefiting Partner Institutions.

Examples of potentially conflicting activities or those requiring prior approval and potential management.

The following activities represent examples of potential or actual conflicts of commitment or interest. While they do not necessarily imply conflict of interest, they do require review and possible management of conflict of interest or commitment by the CEO. The list is not inclusive and is intended to provide guidance. Where noted, activities of this type involving Partner Institutions would generally not be considered conflict of interest or require disclosure; however, it is recommended that the CEO be consulted in any ambiguous situation.

a. Failing to fully meet NMC responsibilities (as agreed to in employment contracts and job descriptions) due to involvement in outside activities.
b. Having an SFI that could directly and significantly affect the design, conduct, or reporting of research or other NMC activity.
c. Using NMC resources to conduct research that is sponsored by an entity in which the employee or his/her family member holds an SFI.
d. Serving in an executive or managerial capacity or holding Significant Financial Interest in for-profit or not-for-profit entities doing business with NMC. (Partner Institutions excluded.)
e. Recruiting NMC employees to other institutions without prior approval by CEO.
f. Serving on either the board of directors or a major advisory committee of an external entity that sponsors the employee's research or provides gift funds for the use of the employee.
g. Utilizing NMC employees in consulting activities and/or research sponsored by an entity in which the employee has financial interests.
h. Conducting testing of products, devices, or services owned or controlled by a business in which the employee or a member of his/her family has a financial interest or receives remuneration.
i. Diverting research or education opportunities from NMC to another academic institution, federal laboratory, business, or consulting entity. (Partner Institutions excluded.)
j. Directing purchasing opportunities to employee's family-owned company or an associated entity.
k. While acting in the context of his/her NMC duties, making professional referrals to a business in which an employee or a member of his/her family has a financial interest.
l. Conducting non-NMC business activities involving NMC employees.
m. Solicitation for funding on behalf of any non-NMC beneficiaries at NMC-sponsored events. (Partner Institutions excluded.)
n. Any outside consulting that could provide the sponsoring outside entity with knowledge or data that may be used to give the outside entity an advantage in

securing IP that otherwise would be secured by the NMC, its Partner Institutions or its research sponsors.

Review of Disclosures and Management of Conflicts of Interest

Employees' COI and Commitment disclosures will be reviewed by the COO (or designee) to determine whether there is any SFI or other COI or Commitment that reasonably appears to be related to NMC activities in which the employee is engaged.

If COO (or designee) concludes that an employee's disclosure reasonably appears to be related to NMC activity, the disclosure and corresponding documentation will be forwarded to the CEO for review.

The CEO will review the documentation and the disclosure to determine whether the SFI or other COI related to the NMC activity appears to directly and significantly affect the NMC activity, including the design, conduct, or reporting of the activity, and thereby constitutes a (F)COI that may need to be eliminated, reduced or managed.

When the CEO determines that there is a Financial or other Conflict of Interest, the CEO works with the conflicted employee to develop a plan to eliminate or manage the (F)COI ("management plan"). The plan shall be implemented either as soon as possible, or, as applicable, before the conflicting NMC activity starts, before accepting funding from the sponsor, or prior to expenditure of research funding. The management plan shall specify the actions that are required to manage the (F)COI, and may include:

a. the role and principal duties of the conflicted employee;
b. conditions of the management plan;
c. how the plan will safeguard objectivity in the NMC research/activity (as applicable);
d. confirmation of the employee's agreement to the plan;
e. how the plan and employee's compliance with the management plan will be monitored on an ongoing basis until completion of the project;
f. how the plan will be modified;
g. other actions may include:

    1. public disclosure of the conflict
    2. divestiture of employee's conflicting financial interests
    3. monitoring of the research by independent reviewers
    4. escrow of an equity interest until certain triggering conditions are met
    5. prohibition on the employee's involvement in contract negotiations
    6. severance of the employee's relationships that create the conflict

7. disqualification of the employee from participation in the NMC activity that would be affected by Significant Financial Interests.

No conflicts may be waived. If a conflict of interest cannot be managed, the employee must withdraw from the research and the NMC may need to decline the award or terminate the sponsored agreement.

Enforcement Mechanisms

The final responsibility for this policy resides in the CEO, who reviews reports of potential conflicts and determines the remedies. If remedies that are mutually satisfactory to the employee and NMC are not reached, the NMC may impose a sanction. Sanctions for violating this Policy depend on the severity of the violation and range from reprimand to dismissal.

In addition, whenever an FCOI is not identified or managed in a timely manner, including

a. failure by the employee to disclose a SFI or other potential COI that is determined by the NMC to constitute a conflict of interest,
b. failure by the NMC to review or manage such a conflict of interest, or
c. failure by the employee to comply with a COI management plan,

the NMC shall, within 120 days of the determination of noncompliance, complete a retrospective review of the employee's activities to determine whether any research, or portion thereof, or other activity conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research or activity. The NMC is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

a. Project number, as applicable;
b. Project title, as applicable;
c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
d. Name of the entity with which the employee has a conflict of interest;
e. Reason(s) for the retrospective review;
f. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
g. Findings of the review; and
h. Conclusions of the review.

Based on the results of the retrospective review, if applicable, the NMC shall update the COI report previously submitted to the awarding agency, specifying the actions that will

be taken to manage the FCOI going forward. If bias is found, the NMC is required to notify the awarding agency promptly and submit a mitigation report to the awarding agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the NMC 's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Depending on the nature of the COI, the NMC may determine that additional interim measures are necessary with regard to the employee's participation in the NMC activity between the date that the conflict of interest or the employee's noncompliance is determined and the completion of the NMC's retrospective review.

Records

The NMC will maintain records of all COI disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the activity to which they relate, or until the resolution of any awarding agency's action involving those records, whichever is longer.

Public Access

The NMC's Conflict of Interest policy is posted on the NMC public website at https://newmexicoconsortium.org/inside-nmc/policies-guidelines/.

Information concerning identified COI related to sponsored research will be made available to any requester within 5 calendar days of a written request to NMC by email (hr@newmexicoconsortium.org) or by mail (4200 West Jemez Road, #301, Los Alamos, NM 87544).