

Monmouth College

Financial Conflict of Interest Policy for Federally Funded Research Grants

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A. Summary

The Federal Government requires Monmouth College to maintain and make available to the public a written policy regarding the identification, management, and disclosure of Investigators' financial conflicts of interest that may, or may reasonably seem to, affect research funded or partially funded by federal grants. The College is also required to provide conflict of interest training to Investigators who design, conduct or report on federally funded research grants. This policy shall fulfill the requirements of applicant and grantee institutions as delineated by the National Institutes of Health and the National Science Foundation.

B. Background

In August 2011, the U.S. Department of Health and Human Services revised its regulations regarding financial conflict of interest held by scientific Investigators conducting research funded by the federal government. The regulations were revised in response to the increasing complexity of relationships among Investigators, private industry, and the government, and the increasing likelihood that such relationships might have, or seem to have, the potential to affect research integrity.

The revised regulations were enacted to ensure that research funded by the Public Health Service (PHS) is free of bias stemming from Investigator financial conflicts of interest (FCOIs). The regulations follow:

- 42 CFR Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Funding is Sought* (pertaining to grants and cooperative agreements)
- 45 CFR Part 94, *Responsible Prospective Contractors* (pertaining to contracts)

NIH awards made before August 24, 2012 are subject to the prior (2005) regulations. Awards made on or after August 24, 2012 are subject to the revised regulations.

In response to the same circumstances, the National Science Foundation also maintains conflict of interest policies that stipulate most of the same requirements of funded institutions, differing slightly in some respects from those of the National Institutes of Health. (NSF 15-1 and NSF 16-1 Award and Administration Guide, Chapter IV--Grantee Standards, A. Conflict of Interest Policies).

C. Purpose

The public relies upon the validity of research conducted in colleges and universities, medical research centers, and other academic research centers. Public funds support much of this research, and it should be held to the highest ethical standards in order for it to benefit society. Institutions receiving federal research funding must therefore insure that Investigators' financial interests do not create unacceptable risks to research integrity.

The government regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of federally funded research will be free from bias resulting from Investigators' financial interests.

D. Disclosure of Significant Financial Interests

Who must disclose

All individuals who are responsible for the design, conduct, or reporting of research funded, or proposed for funding, by NIH, NSF, FDA, or other federal agencies ("Investigators") are required to disclose to the College the Significant Financial Interests (SFIs) of self, legal spouse, and dependent children.

Investigator is defined as principal Investigator (PI), co-PI, project director (PD), co-PD, or any other person—regardless of title or position—who is responsible for the design, conduct, or reporting of research funded, or proposed for funding, by NIH, NSF, or other federal agency. In some circumstances, this may include Senior Personnel, collaborators or consultants. In general, this does not include undergraduate researchers or trainees, but it may under certain circumstances.

When and how disclosures are made

Each Investigator subject to this policy must submit a written disclosure regarding Significant Financial Interests *before* a federal research proposal is submitted. These disclosures must be updated in writing:

- Annually within the period of the federal award including any extensions, during the month of January; *and*
- Within 30 days of discovering or acquiring a new Significant Financial Interest within the period of the federal award, including any extensions.

Investigators shall be make these disclosures using a form and process that Monmouth College administers through the Office of Corporate, Foundation, and Sponsored Research Support.

What must be disclosed

Each Investigator subject to the policy must disclose all Significant Financial Interests (SFIs)—their own, as well as those of any spouse, legal partner, and dependent children—that reasonably appear to be related to the Investigator's institutional responsibilities.

Institutional responsibilities are defined as teaching, research, service to the College, and any other professional work undertaken as an employee of Monmouth.

Significant Financial Interests (SFIs) are defined as things of monetary value (whether or not the value is readily ascertainable) received or owned by the Investigator or by the Investigator's spouse, legal partner, or dependent children. For all SFIs described below, the aggregated value of interests received or owned by the Investigator, the Investigator's spouse or legal partner, and the Investigator's dependent children should be used to determine whether disclosure is necessary and what information to disclose.

Types of SFIs include: equity (stock, stock options, ownership) in publicly or privately held companies; salary or other payments for services; reimbursed or sponsored travel; and intellectual property rights.

1. With regard to any *publicly traded entity*, a Significant Financial Interest exists if the combined value of any equity interest as of the disclosure date plus any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$5,000.
2. Equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
3. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
4. With regard to any *non-publicly traded entity*, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or spouse, legal partner, or dependent children) owns any equity interest in the entity, regardless of dollar value.
5. Income (e.g., royalties) from intellectual property rights and interests (e.g., patents, copyrights), except that covered under Exception #1 (below).
6. Sponsored or reimbursed travel related to the Investigator's institutional responsibilities, except for travel covered under Exception #4 (below).

Exceptions. The term Significant Financial Interest does not include the following:

1. Salary, stipends, royalties, or other remuneration paid by Monmouth College to Investigators employed or appointed by Monmouth. This includes any intellectual property rights assigned to the College, and agreements to share in royalties related to such rights.
2. Income from investment vehicles, such as mutual funds and retirement accounts, need not be disclosed so long as the Investigator does not directly control the investment decisions made in these vehicles.
3. Income from seminars, lectures, or teaching engagements sponsored by—or services on advisory committees or review panels for—a federal, state, or local government, institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.
4. Travel reimbursed or sponsored by Monmouth, or by a federal, state, or local government, institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with any institution of higher education.

E. Determination and Management of Significant Financial Interests

Disclosures made under this policy will be reviewed by Monmouth's Vice President for Finance and Business, who will be responsible for determining:

1. Whether the SFI is related to the federally-funded research, or could reasonably seem to be related: i.e., whether it could be affected by the federally-funded research or is an entity whose financial interest could be affected by the research. The Vice President for Finance and Business may involve the Investigator in this review.
2. If the Vice President for Finance and Business determines an SFI is related to, or could reasonably seem to be related to, the federally-funded research, he or she shall then reasonably determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the federally-funded research (i.e., whether the SFI is a Financial Conflict of Interest).

For an initial disclosure, this review shall take place prior to any expense being charged to the grant fund account. For subsequent disclosures, this review shall take place within 60 days.

If the Vice President for Finance and Business determines that a Financial Conflict of Interest exists, he or she shall work with the Investigator (and any others who may be appropriate, such as the Vice President for Academic Affairs/Dean of the Faculty, faculty or staff with relevant expertise, and/or outside experts) to either eliminate the conflict or develop a management plan.

If an FCOI is promptly eliminated (through means such as selling an equity interest, severance of relationships that create financial conflicts, or change of grant personnel or personnel responsibilities), then the FCOI no longer exists and does not need to be reported.

If eliminating the FCOI is not feasible or desirable, a plan shall be developed to manage the conflict. The plan shall include:

- Name, role, and principal responsibilities of the conflicted Investigator.
- Project title and federal award number.
- Explanation of the nature of the FCOI, including the name of the entity with which the conflict exists and the approximate dollar value of the SFI (or a statement that the value is not readily ascertainable).
- Conditions of the management plan and how compliance with these conditions will be monitored.
- Justification of how the management plan is reasonably expected to safeguard objectivity in the design, conduct, and reporting of the research project.
- Confirmation that the conflicted Investigator and the Vice President for Finance and Business agree to the plan.
- Other information as determined by the Vice President for Finance and Business to be appropriate.

Actions that may be specified in the management plan to safeguard the integrity of the research enterprise may include, but are not limited to: public disclosure of financial conflicts of interest in all publications and presentations based upon the research; divestiture of the financial interest; monitoring of the research by an independent reviewer; modification of the research plan; change of personnel or personnel responsibilities, or disqualification of the conflicted personnel from participation in all or a portion of the research.

Monmouth College will report each FCOI and management plan in compliance with the sponsoring federal agency's requirements.

If, for whatever reason, an FCOI is not disclosed or managed in a timely manner and research work has been undertaken while the conflict exists, the VPFB may convene a task force to conduct a retrospective review; to determine whether the FCOI resulted in any bias in the design, conduct, or reporting of federally-supported research; and to recommend a mitigation plan if necessary. This retrospective review shall be undertaken, and its findings and recommendations reported, in a manner consistent with the requirements of the sponsoring federal agency.

Subrecipients

Monmouth College must take reasonable steps to ensure that all subrecipients of federal research award funds granted to it comply with federal regulations regarding Financial Conflicts of Interest. To that end, the College will include, in written agreements with each subrecipient, terms that specify whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. If the subrecipient institution's policy will be used, the agreement will further include a certification that the subrecipient institution has adopted and enforces FCOI policies that comply with applicable federal regulation, and will specify the timing of subrecipient reports to Monmouth College of identified FCOIs such that Monmouth can timely complete its FCOI report (if any) to the sponsoring federal agency.

F. Required FCOI Training, FCOI Policy Administration and Enforcement

Required FCOI training shall be provided to Monmouth College Investigators by the office of Corporate, Foundation, and Sponsored Research Support. This training will be required:

1. Before submittal of a new Federal research grant, by each proposed Investigator (as defined previously) under the grant. This training must be completed before the proposal is submitted.
2. Of any Investigator who has not participated in FCOI training in the prior four years.
3. Of all Investigators, any time Monmouth College revises this policy or related procedures in a manner that affects the requirements of Investigators.
4. Of an Investigator is new to Monmouth College.
5. Any time Monmouth College finds that an Investigator is not in compliance with this FCOI policy or an FCOI management plan.

The Office of Corporate, Foundation, and Sponsored Research Support will solicit financial disclosures during the proposal development process and annually during the award during the month of January, and will also collect financial disclosure statements on behalf of the Vice President for Finance and Business.

Documentation relating to the implementation of this policy—including financial disclosures, the determinations of the Vice President for Finance and Business, FCOI management plans, and evidence of plan monitoring—will be maintained as part of the record for each applicable federal research proposal or award for at least three years after the final financial report is submitted. These documents will be treated as confidential records similar to other grant documents containing salary or other personal financial information.

Investigators are required to comply with this policy as a condition of applying for and receiving federal research grants administered by Monmouth College. Investigators failing to comply with this policy may be subject to disciplinary proceedings and sanctions as appropriate under the relevant institutional policies for faculty, staff, or students.

This policy shall be made publicly available on the Monmouth College website. Information on identified FCOIs held by senior/key personnel shall be provided by written response to any requestor within five business days of a request.