

Marist College Financial Conflict of Interest Policy

I. Introduction

Marist College is obligated to ensure that its teaching, research, and student mentorships are held to the highest standards. The College is also responsible for safeguarding public trust in any of its expenditures of external research funding. Marist, therefore, must implement guarantees to the Marist community, its external funders, and the public at large that its officials, faculty, staff and others involved in research are held to the highest standards and will avoid or mitigate financial conflicts of interest, whether they are real or perceived.

For these reasons, Marist College has put in place administrative requirements and processes to identify and manage financial conflicts of interest (FCOI) associated with all research projects for which external funding is sought or accepted. Marist actively promotes and monitors investigator cooperation with specific agency guidance and regulations for FCOI disclosure, management, and reporting. To comply with NIH's 2020 requirement for FCOI institutional policies, for example, Marist has made this FCOI policy available on ERA Commons and publicly available on the Office of Academic Grants website.

II. Significant Financial Interests, Definitions, and Examples

A ***significant financial conflict of interest*** refers to a financial gain that has the potential to compromise an investigator's decisions, actions, and objectivity related to the research design, conduct or reporting. It refers to as anything of monetary value, including but not limited to salary or other payments for service (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights), *where such payments are \$5,000 or more annually; the equity interest exceeds five percent ownership and has a value of \$5,000 or more at fair market value, or royalty payments are \$5,000 or more annually.*

Significant financial interests are inclusive of the financial interests of the investigator and/or the investigator's spouse, dependent children, or domestic partner. Financial gains of \$5,000 or more within the past 12 months or gains expected in the next 12 months must be disclosed. A plan for managing the financial conflict of interest must be in place before the acceptance of external funds.

"Investigator" refers to the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of a project funded by the PHS, or proposed for such funding. With respect to financial interests, "investigator" includes the investigator's spouse and dependent children.

Exemptions to financial interests include: (1) salary, royalties, or other remuneration from the Marist; (2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (3) income from service on advisory committees or review panels for public

or nonprofit entities; or (4) financial interest in business enterprises or entities if the value of such interest does not exceed \$5,000 or represent more than five percent ownership interest for any other enterprises or entities when combined for the investigator and the investigator's spouse and dependent children.

For all grant applications or contract proposals (new or continuing), information on "*significant financial interests*" that would reasonably appear to be affected by the project must be provided by any investigator responsible for the design, conduct or reporting of externally funded projects. Information must be provided on a separate disclosure form before an application submission. Prior to the acceptance of an award, the institution must resolve any conflicts in financial interests (i.e., those that could directly and significantly affect the design, conduct, or reporting of the sponsored project). Any change in significant financial interest prior to or during the award period must be disclosed at the time of change.

Examples of significant financial interests that must be disclosed include the following:

- Remuneration from increased value of publicly traded equities or non-publicly traded equities
- Paid services (other than scholarly or academic work) from US or foreign entity, including but not limited to nonprofit, educational institution, corporation, medical, or government entity
- Income, including royalties, from intellectual property paid by an entity other than Marist College
- Reimbursed travel or sponsored travel for the investigator and/or investigator's family/domestic partner (including purpose of trip, sponsor/organizer, destination, and duration). Marist will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

Examples of significant financial interests in excess of \$5,000 that DO NOT need to be disclosed include the following:

- Income from Marist
- Income from scholarly work or publications
- Income from seminars, review panels, teaching engagements, workshops, work on advisory or review panels that are sponsored by US federal, state, or local government entities
- Income from equity investments that the investigator does not control such as mutual funds and retirement accounts.

III. Identifying and Managing Financial Conflict of Interest (FCOI)

All investigator FCOI disclosures are reviewed and responded to with a management plan prior to any spending on an award. Marist College requires all principal investigators (PIs) and co-principal investigators (Co-PIs), and anyone involved in the research including investigators on subawards under a grant, to identify if they have a significant financial conflict of interest with respect to a proposed grant application prior to the proposal's submission to a funding agency. FCOI forms are available on the Office of Academic Grants' website and signed forms are kept on file in the Office of Academic Grants for all active grant applications.

Prior to Submission of a Grant Application

Steps before an application is submitted to an agency are as follows:

- 1) The Academic Grants Office must receive a signed FCOI certification form from the investigator(s) that states whether a significant conflict of interest exists. This form must be received from all investigators prior to circulating the grant application for preliminary institutional approvals.
- 2) If an investigator indicates that no significant conflict of interest exists, the Academic Grants Office keeps the signed FCOI form on file. FCOI forms are kept on file for all pending and active grant applications. For awarded proposals, the FCOI is kept on file for 3 years after grant close out or agency reviews are complete.)

If an investigator discloses a significant conflict of interest during the proposal preparation process, the following steps are taken.

- 1) the investigator provides the Academic Grants Office with a signed disclosure form with details of the conflict in a sealed envelope.
- 2) The Academic Grants Office delivers the sealed envelope to the Associate Vice President of Academic Affairs within 48 hours.
- 3) The Associate Vice President of Academic Affairs reviews the financial conflict of interest disclosure and establishes if 1) the investigator's significant financial interest could be affected by the research or 2) the research itself could be impacted by the investigator's financial interest.
- 4) If a significant conflict of interest is identified, the Associate Academic Vice President of Academic Affairs determines a plan to manage the conflict and submits a FCOI report (see II. FCOI Report below) to the agency within 60 days of the investigator's disclosure.
- 5) Records of all disclosures will be maintained in the Office of the Associate Vice President for Academic Affairs.

Disclosure of Significant Financial Conflicts of Interest Upon or During Award

If an investigator has a significant conflict of interest at the time of award or during an active award, the investigator must take the following steps.

- 1) As soon as an investigator becomes aware of a significant financial conflict of interest, the investigator must fill out and submit a Financial Conflict of Interest Disclosure to the Associate Vice President for Academic Affairs.
- 2) A review will be conducted to determine if a significant financial conflict of interest exists.
- 3) If a significant financial conflict of interest is found to exist, a management plan to reduce or eliminate the conflict will be put in place and the management plan and report will be submitted to the funding agency.
- 4) Records of all disclosures will be maintained in the Office of the Associate Vice President for Academic Affairs.

IV. The FCOI Report

Once a significant financial conflict of interest is identified, the Signing Official (SO) is responsible for reporting the financial conflict of interest to the agency with a management plan within 60 days. Ongoing FCIO management reports will be submitted at the time that progress reports are submitted to the agency. These FCIO reports will be submitted by the signing official and provide any updates or changes to the management plan (including whether or not the management plan is still in progress or discontinued because the financial conflict has ended).

The FCOI report will include the following:

1. Any initial steps taken to mitigate the FCOI;
2. Investigator duties related to the research;
3. Scope and conditions of the management plan;
4. Explanation of how the management plan aims to ensure research objectivity;
5. Documentation of the investigator's agreement with the plan;
6. Steps taken to monitor the management plan and to confirm investigator compliance;
7. Other information as requested by the agency

V. Investigator or Institutional Noncompliance and Retrospective FCIO Review

1. In the event that an investigator fails to disclose a significant financial conflict of interest and one is known to exist, the Associate Vice President for Academic Affairs must implement a management plan with details on what steps have been (or will be taken) to manage the conflict.
2. In the event that the Institution fails to review a FCOI on an active award, the institution's designated official(s) must review and enact a review and FCOI

management plan and submit a report to the agency that specifies actions that have taken place as well as those that are planned.

3. Within 120 days of the date that noncompliance was first determined, the institution is obliged to complete and submit a *retrospective review* all of the investigator's research activities (funded and unfunded) during the time frame of noncompliance.
4. The retrospective review must evaluate whether any portion of the funded research during the period of noncompliance was compromised (biased) in its department, design, or reporting.
5. If any bias was found during the retrospective review, it should be documented and the agency must be contacted by submitting a report describing the impact of the bias on the research as well as a plan mitigate or eliminate the biases documented in the retrospective review.
6. After the retrospective review, subsequent FCOI reports must be updated with any steps to be taken moving forward and follow the regular reporting schedule.

VI. Reports to the Agency

Agencies may have different processes for submitting FCIO reports and specific agency requirements should be verified before the submitting an FCOI report. While others may be involved in writing an FCIO report, only a signing official at Marist College can submit FCIO reports and respond to correspondence and requests for additional information.

Below are the instructions for submitting a FCOI Report to the NIH and NSF.

NIH FCIO Reports: The Associate Vice President for Academic Affairs will submit FCIO reports through the NIH FCOI Module on ERA Commons.

NSF FCIO Reports. The Associate Vice President for Academic Affairs will submit FCIO reports to the NSF's Office of General Counsel as appropriate and keep this office informed of all actions taken to manage FCIOs. The NSF Office of General Counsel will be advised of any restrictive measures that are part of the management plan. If the NSF reviewers find the actions taken are ineffective, inequitable, or interfere with scientific progress and that the benefits of scientific progress outweigh the FCIO concerns, the NSF may recommend that the research move forward without the management plan restrictions.

VII. Point of Contact for FCOI Reviews, Management Plans, and Disclosures

The Associate Vice President for Academic Affairs will serve as the point of contact for all FCOI reviews, involve others as needed, and oversee the FCOI management plans and reporting. Additional responsibilities of the Associate Vice President for Academic Affairs include, but are not limited to, the following

- a. Determining if and when an investigator's FCIO is eliminated and reporting updates to the NIH when the next annual report is due. (After the update, subsequent FCIO reports will no longer be required.)
- b. Providing access to anyone aiding in the review or resolution of an FCOI to the FCIO Module on ERA Commons.
- e. Maintaining records of all financial disclosures and management plan records for at least 3 years or until an agency's resolution of actions related to the records (which could be longer).
- c. Assigning conditions or restrictions to manage, reduce or remove financial conflicts of interest. See examples of restrictions below.

VIII. NSF Examples of Conditions and Restrictions for Mitigating or Eliminating FCOI

The NSF cites the following examples of measures that might be introduced as part of a management plan to mitigate or eliminate FCOIs.

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
- divestiture of significant financial interests; or
- severance of relationships that create conflicts.