

UNIVERSITY OF MAINE

**Policies and Procedures for
Financial Disclosures and Conflicts of Interest
in Extramurally Sponsored Activities**

**Office of the Vice President for Research and Dean of the Graduate School
Office of Research Compliance**

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**Policies and Procedures for
Financial Disclosures and Conflicts of Interest (COI)
in Extramurally Sponsored Activities**

Declaration of Policy

The University of Maine is committed to preserving and furthering ethical conduct, institutional integrity, and public confidence in research pursuits. University of Maine personnel engaged in extramurally funded work shall act at all times in a manner consistent with their public responsibilities to the University and shall exercise particular care that no detriment to the University results from conflicts between their personal financial interests and the interests of the University. Such interests can threaten – or seem to threaten – the integrity of educational programs and research agendas, the free dissemination of scholarship, and the appropriate use of public resources for public benefit. Accordingly, investigators shall disclose all significant financial interests they may have in extramurally funded work, and shall adhere to any conditions or restrictions imposed by the University to manage, eliminate, or reduce conflicts relating to those interests.

This policy outlines the obligations of University personnel to disclose significant financial interests and the responsibility of the University to review such information and take appropriate steps to manage, reduce, or eliminate related conflicts. Certain financial interests are inherent in the incentive structure of the academic enterprise. Such incentives are not inherently bad and are indeed motivating forces for diligence in research. It is not the intent of this policy to prohibit all extramurally sponsored activities in which investigators hold a more easily defined significant financial interest, however, it is required that these interests be disclosed and that the project be conducted in such a way that such interests do not compromise, or appear to compromise, an investigator's professional judgment in conducting projects or reporting results.

This policy complies with, and is guided by, the U.S. Department of Health and Human Services (USDHSS) Public Health Service (PHS) regulations (42 CFR Part 50 § F and 45 CRF Part 94.

Applicability

This policy applies to all University employees and students who serve as investigators in proposals submitted to external sponsors. Sub-awardees and their personnel, and collaborators of other institutions (collectively 'Sub-Awardees') must either comply with this policy or document that their institutions or organizations are in compliance with USDHHS PHS rules by certifying that: (a) their company or institution has a financial conflict of interest policy that is compliant with USDHHS PHS rules; and (b) they have received COI training; and (c) if necessary, they have made COI disclosures as required by their institution's or company's COI policy; or (d) **they cannot so certify and will be subject to the University of Maine's COI policy.**

Definitions

A **Conflict of Interest** is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Investigator refers to the Project Director/Principal Investigator, any other person identified as Senior/Key personnel in a grant application, progress report, or other report submitted to an external sponsor, and others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research.

Significant Financial Interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Specifically **excluded** from the definition of Significant Financial Interest are:

- (1) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- (2) Incomes from service on advisory committees or review panels for public or nonprofit entities.
- (3) Investments in mutual funds or retirement programs if the investigator has no practical control over the management of those investments.
- (4) Royalties paid by the University.

- (5) Regular salary, summer salary, or overload compensation paid by the University when the rate of compensation is set by the University. (Note: consulting fees or other forms of overload compensation paid by the University at rates other than that established by the University are not necessarily excluded from the definition of significant financial interest; see item 7 below.)
- (6) An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children satisfy both of the following conditions: (a) does not exceed \$5,000 in value as determined through reference to public prices or other measures of fair market value, and (b) does not represent more than a 5% ownership interest in any single entity.
- (7) Overload salary, consulting fees, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the prior twelve months have not exceeded \$5,000 and over the next twelve months are not expected to exceed \$5,000.

Obligation to Disclose Financial Interests

By submitting a [*Significant Financial Interest Disclosure Form*](#), each University employee and student who serves as an investigator on proposals submitted to external sponsors must disclose for himself or herself, and for his or her spouse and dependent children –

- (a) all significant financial interests that would reasonably appear to be affected by the activities funded or proposed for funding, and
- (b) all significant financial interests in entities whose financial position would reasonably appear to be affected by activities funded or proposed for funding.

Regardless of the above minimum requirement, an investigator in his or her best interest may choose to disclose other financial or related interests that could present, or be perceived to present, a conflict of interest. Also, it is not possible to specify all the possible personal relationships or business arrangements which might result in significant financial interests for University personnel engaged in extramurally sponsored activities. In completing a Financial Disclosure Statement, however, University personnel are expected to follow the spirit of this Policy and disclose other financial interests that might be anticipated to threaten the same harm. For example, the financial interests of a parent, sibling, independent child, unmarried domestic partner, or a close associate may be perceived as grounds for the same kind of conflict of interest, and should be reported, if known. Similarly, the promise of future gifts, or

the offer of a loan on advantageous terms not available to the general public, might represent a disclosable significant financial interest.

Financial Conflict of Interest Training and Investigator Certification

Prior to submitting a proposal, each named Investigator must successfully complete UMaine's training on COI and submit an *Investigator Conflict of Interest Certification*, specifying whether s/he has any significant financial interest relating to the proposed activity. All other investigators will successfully complete UMaine's training on COI and submit an *Investigator Conflict of Interest Certification* before they may be supported with award dollars.

Financial Conflict of Interest Disclosure

Any investigator having a significant financial conflict of interest shall complete a [Significant Financial Interest Disclosure Form](#) and submit it with supporting documentation that specifies all business enterprises or entities involved and the nature and amount of each interest. All documentation must be submitted to the Office of Research Compliance; **this information must be received before a proposal will be submitted by the Office of Research Administration.**

At the investigator's option, the supporting documentation may also include a proposed Conflict of Interest Resolution Plan. The Office of Research Compliance will treat disclosures and supporting documents as confidential materials prepared for the Financial Disclosure Review Committee, however, please note that pursuant to PHS regulations, disclosure forms provided to the University in connection with PHS-funded projects must be made publicly available upon request.

In addition, each investigator disclosing a significant financial interest shall describe such interest in the proposal narrative or in an attachment thereto, to make certain that the potential sponsor will be fully aware of the possibility of a conflict of interest situation before a final decision on the potential award is made (see Appendix III).

Review of Disclosures

A standing Financial Disclosure Review Committee (FDRC) shall be responsible for (a) reviewing financial disclosures, (b) developing or approving plans to manage or eliminate conflicts of interest, and (c) advising the campus community about this policy. The Committee shall be comprised of the Vice President for Research and Dean of the Graduate School (Chair), the

Director of Research Administration, the Vice President for Innovation and Economic Development, the Director of Research Compliance (Secretary), and the Chair of the Research and Scholarship Committee of the Faculty Senate, and one tenured faculty member from each College, appointed by their respective Deans to be staggered for three-year terms.

The Vice President for Research and Dean of the Graduate School, in consultation with the Director of Research Administration and the Vice President for Innovation and Economic Development shall conduct an initial review of all financial disclosures to determine whether a conflict of interest exists. A conflict of interest exists if a reasonable determination can be made that a significant financial interest could directly and significantly affect the design, schedule, conduct, or reporting of the activities proposed for funding. If the initial determination is made that there is a conflict of interest covered by this policy, then the disclosure packet will be referred to a Subcommittee of the FDRC.

Prior to consideration by the Subcommittee of the FDRC, the investigator, in cooperation with the investigator's academic department or unit, shall develop and submit to the Director of Research Compliance a Conflict Resolution Plan that details proposed steps that will be taken to manage or eliminate any conflict of interest presented by the investigator's financial interests.

The Chair will appoint the Subcommittee of the FDRC to review and act on each Conflict Resolution Plan. Normally a Subcommittee will be comprised of eight members; five ex-officio members of the Committee (Vice President for Research and Dean of the Graduate School, the Director of Research Administration, the Vice President for Innovation and Economic Development, the Director of Research Compliance, and the Chair of the Research and Scholarship Committee of the Faculty Senate), plus three tenured faculty members appointed by the Chair. In the event members of the Subcommittee are unable to serve in a timely manner, or have a relationship to the individual making the disclosure that represents a potential conflict of interest, or if in the judgment of the Chair, other circumstances warrant restructuring the Subcommittee, the Chair may appoint an alternative Subcommittee of no fewer than five members to act on behalf of the FDRC.

The Subcommittee shall review the Conflict Resolution Plan and approve it, disapprove it, or require modifications, conditions, or restrictions. Such conditions or restrictions may include, without limitation: (a) public disclosure of significant financial interests; (b) monitoring of the funded activities by independent reviewers; (c) modification of the planned activities (which may be subject to sponsor approval); (d) disqualification from participation in all or a portion of the project; (e) divestiture of significant financial interests; (f) severance of relationships that

create conflicts; (g) appointment of an alternate PI; or (h) appointment of an individual to provide independent technical or financial oversight.

The Subcommittee may, at its discretion, invite individuals with special expertise, including legal counsel, to assist the members in reviewing and resolving complex issues. These individuals may not vote with the Subcommittee. A Subcommittee may also, at its discretion, invite the person whose disclosure statement is under review to attend meetings, participate in discussions, and/or provide supplementary clarifying information.

The Office of Research Compliance will be responsible for monitoring compliance with approved Conflict Resolution Plans. The Subcommittee shall specify the type and frequency of reporting required, but in no instance should reporting be less than once per year.

If the Subcommittee determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, the Subcommittee may allow the research to go forward without imposing conditions or restrictions.

Time Schedule

The Vice President for Research and Dean of the Graduate School shall normally decide within ten (10) days whether a potential conflict of interest exists. If so, the investigator will be asked to prepare a proposed Conflict Resolution Plan, and the Financial Disclosure Review Subcommittee shall normally act on that plan with thirty (30) days of its receipt. The Subcommittee may decide to extend the review period by up to an additional thirty (30) days when such a delay is warranted by the complexity of the circumstances.

Whereas investigators must disclose significant financial interests before a proposal is submitted to an external sponsor, the Conflict Resolution Plan, if any, does not need to be finalized until just prior to acceptance of the award. The time duration between the submission of a proposal and the offer of any award varies greatly from a few days, in some instances, to more than a year in others; and of course, not all proposals result in awards. In view of these circumstances, the principal investigator or project director may request that the review of all disclosures relating to the subject proposal be deferred until such time as an award is offered. In that event, the time schedule outlined above will still apply; only the starting point is delayed.

Reconsideration of Conflict Resolution Plans

Final responsibility for the review of financial disclosures and approval of a Conflict Resolution Plan is vested with the Financial Disclosure Review Subcommittee. In the event that the resolution plan specified by the Subcommittee is unacceptable to the investigator whose interests have been disclosed, he or she may request reconsideration, and may meet with the Subcommittee to explain why the plan is unacceptable and to propose changes. The request for reconsideration shall be in writing and shall be submitted to the Subcommittee via the Director of Research Compliance. Upon receipt of such a request, the Subcommittee shall have thirty (30) days in which to consider the changes proposed, or other modifications deemed appropriate, and to issue its final resolution plan.

There are no further provisions for reconsideration or appeal within this policy. If the Subcommittee's requirements remain unacceptable to the Principal Investigator or Project Director of a proposed project, the University shall decline the award. If the Subcommittee's requirements are unacceptable to another of the project's investigators, the University shall seek sponsor approval to replace that investigator.

Further Administrative Approval

Conflict Resolution Plans approved by a Financial Disclosure Review Subcommittee may be disapproved, or approved with additional terms and conditions by the Provost, President, or by any other University officer designated by the President. However, no officer of the University may approve a Conflict Resolution Plan which does not include as a minimum all terms and conditions approved by the Subcommittee.

Certification of Compliance

Each person judged to have a conflict of interest must sign an agreement certifying that he or she will adhere to all conditions or restrictions imposed by the Subcommittee and will cooperate fully with any individual(s) assigned responsibility for monitoring compliance. The University will not accept an award until the Director of Research Compliance has received signed Certifications of Compliance for all project personnel judged to have a conflict of interest.

Updating Financial Disclosures

All investigators are responsible for updating information on new reportable significant financial interests, such that accurate and current information is on file with the University at all times. New reportable significant financial interests include financial interests that become reportable due to an increase in value that meets the reporting threshold, as well as the acquisition of new interests that are reportable. Updated financial disclosures must be submitted to the Director of Research Compliance within fifteen (15) days of the reportability of such interests, either during the period of a funded project or during the period in which a decision on a proposal is pending.

When an updated Significant Financial Interest Disclosure Form is received during the period of an ongoing project, the Vice President for Research and Dean of the Graduate School, in consultation with the Director of Research Administration and the Vice President for Innovation and Economic Development, shall review the updated information within ten (10) days of its receipt and decide whether it causes a conflict not already satisfactorily managed, reduced, or eliminated under the current Conflict Resolution Plan. If it is decided that a new conflict is not already satisfactorily managed or eliminated under the current Conflict Resolution Plan, the investigator shall have ten (10) days to prepare and submit a new or revised Conflict Resolution Plan, and the Financial Disclosure Review Subcommittee shall have an additional thirty (30) days in which to act upon it. After receiving the determination of the Subcommittee, the person making the updated disclosure shall then have ten (10) days to: (a) sign a certification to abide by any new conditions or restrictions imposed by the Subcommittee, (b) seek reconsideration by the Subcommittee, or (c) terminate participation in the funded project.

If an updated disclosure statement is received by the University while a decision on a proposal is pending, the University shall defer acceptance of the related award until the Vice President for Research and Dean of the Graduate School, and if necessary, a Financial Disclosure Review Subcommittee has reviewed and acted on the updated information, and the investigator has certified compliance with any new terms and conditions.

Individuals not listed as investigators in proposals, but who later assume such roles through hiring, promotion or other means, shall complete training on COI and submit an *Investigator Financial Conflict of Interest Certification* before beginning work on the project as an investigator:

- (a) If the individual (including the individual's spouse and dependent children) has no significant financial interests related to the project, work may begin immediately upon submitting written certification of that fact.

- (b) If significant financial interests exist, the individual shall delay work on the project until a [Significant Financial Interest Disclosure Form](#) has been filed and acted upon, and he or she has certified compliance with the Conflict Resolution Plan, if any, as above.

Reporting

All investigators must submit a Financial Conflict of Interest (COI) Resolution Reporting Form for the project at least annually or more frequently if so required. While the Office of Research Compliance will send a notice to investigators, it is ultimately the investigator's responsibility to adhere to this requirement.

The Vice President for Research and Dean of the Graduate School will report the actions of the Financial Disclosure Review Committee to the Provost and President. The Director of Research Administration will also report the existence of conflicting interests, financial disclosures, and/or related Conflict Resolution Plans to the sponsor of the relevant project, if (a) such reporting is required by the pertinent program regulations or guidelines, (b) the University finds that it is unable to manage or eliminate a conflict of interest, or (c) the failure of an investigator to comply with this policy has biased the design, conduct, or reporting of the research. In the last case, report will also be made of corrective action taken or to be taken.

Record Keeping

The Office of Research Compliance shall be responsible for maintaining records related to all disclosures, associated reviews and actions (whether or not a disclosure resulted in a determination of a financial conflict of interest), reporting/updating information, etc. The records shall be maintained for a minimum of three (3) years after the date of the termination or completion of the corresponding funded project, or the resolution of any audit or legal action involving the records.

Enforcement

Whenever an investigator has violated this policy or the terms of an approved Conflict Resolution Plan, the FDRC shall recommend sanctions which may include disciplinary action ranging from a letter of reprimand to termination of employment. If the violation results in a

collateral proceeding under the [University's Policy and Procedures on Alleged Misconduct in Research and Other Scholarly Activities](#), the FDRC shall defer its recommendation until the collateral proceeding is completed. The FDRC shall present its recommended sanctions to the Provost and President who shall decide on specific sanctions and their implementation.