UNIVERSITY OF MAINE

Policies and Procedures For Financial Disclosures and Conflicts of Interest In Extramurally Sponsored Activities

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Policies and Procedures For Financial Disclosures and Conflicts of Interest In Extramurally Sponsored Activities

Declaration of Policy:

To ensure continued confidence of the people of Maine in the University, 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.

Applicability:

This policy and the requirement for financial disclosure take effect on August 24, 2012, and apply to all University employees and students who serve as investigators in proposals submitted to external sponsors on or after this date. Collaborators of other institutions must either comply with this policy or provide certification that their institutions are in compliance with Federal policies regarding disclosure of significant financial interests and that their portion of the project is in compliance with their institutional policies.

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 those individuals responsible for the design, conduct, and reporting of activities funded or proposed for funding by an external sponsor. This would normally include all individuals

listed as Principal Investigator/Project Director, Co-Investigator/Co-Director, and others so responsible who are not supervised by any of the above.

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 children, satisfies both the following conditions: (a) does not exceed \$10,000 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. 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 \$10,000 and over the next twelve months are not expected to exceed \$10,000.

Obligation to Disclose Financial Interests:

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 filing a Financial Disclosure Statement, however, University personnel are expected to follow the spirit of the 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 Disclosure Statements:

Each investigator shall specify in the Project Approval Routing System (PARS), whether he or she has a significant financial interest relating to the proposed activity. Each investigator having such an 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 concurrently with the proposal submission to the Office of Research and Sponsored Programs following normal University procedures. At the investigator's option, the supporting documentation may also include a proposed Conflict of Interest Resolution Plan. The Office of the Vice President for Research (of which ORSP is a part) will treat disclosures and supporting documents as "CONFIDENTIAL" materials. All required financial disclosures must be on file in the Office of Research and Sponsored Programs prior to the submission of any proposal to an external sponsor.

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.

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, reduce, or eliminate conflicts of interest, and (c) educating the campus community about this policy. The Committee shall be comprised of the Vice President for Research (Chair), the Director of Research and Sponsored Programs (Secretary), the campus Patent and Licensing Officer, the Chair of the Research and Public Service 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, in consultation with the Director of Research and Sponsored Programs and the campus Patent and Licensing Officer 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 the FDRC

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

The Chair will appoint a subcommittee of the FDRC to review and act on each Conflict Resolution Plan. Normally a subcommittee will be comprised of seven members; the four ex-officio members of the Committee plus three tenured faculty member s 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 which 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 full Committee

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; (3) divestiture of significant financial interests; or (f) severance of relationships that create conflicts.

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 to clarifying information.

The subcommittee may designate an individual or individuals responsible for monitoring compliance with its Conflict Resolution Plans. When this option is exercised, the subcommittee shall also specify the type and frequency of reporting required.

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 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 a 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 and Sponsored Programs. Upon receipt of such a request, the subcommittee shall have thirty (30) days in which to consider 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 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 and Sponsored Programs has received signed Certifications of Compliance for all project personnel judged to have a conflict of interest.

Updating Financial Disclosures:

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 and Sponsored Programs with 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.

If an updated disclosure statement is received by the University during the period of an ongoing project, the Vice President for Research 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 so decided, 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. 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 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 late assume such roles through hiring, promotion or other means, shall submit a Financial Disclosure Statement 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 to the Director of Research and Sponsored Programs.
- (b) If significant financial interests exist, the individual shall delay work on the project until the financial information is acted upon, and he or she has certified compliance with the Conflict Resolution Plan, if any, as above.

Record Keeping:

Financial disclosures, and updates thereof, shall be submitted to the Director of the Office of Research and Sponsored Programs who shall be responsible for keeping records of all disclosures and associated actions. No proposal may be submitted to an external sponsor on behalf of the University until the Director or his designee has received all Financial Disclosure Statements related to that proposal.

The Director of Research and Sponsored Programs shall maintain all records of disclosures and related actions 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 or 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 recommendations to the President who shall decide on sanctions and their implementation.

Reporting:

The Financial Disclosure Review Committee reports its actions to the President. The Director of Research and Sponsored Programs 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, reduce, 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.

Procedures Relating to Applications Submitted to the National Institutes of Health and other U.S. Public Health Service Entities

The U.S. Public Health Service, which includes the National Institutes of Health, has issued new rules relating to conflicts of interest, and potential conflicts of interest. The new rules go into effect on August 24, 2012 and can found at:

- <u>42 CFR Part 50 § F</u> PHS Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- <u>45 CFR Part 94</u> PHS Responsible Prospective Contractors

Investigators seeking support from NIH or other U.S. Public Health Service entities should review the new rules, and complete and submit to ORSP the disclosure form which appears as APPENDIX III to this policy document.

If and when the new Public Health Service rules conflict with the COI policies of the University presented in this document, the Public Health Service rules should be followed.

[Note: During the Fall Term of academic year 2012-2013, the VPR will convene an ad hoc committee of the University Research Council to review the new PHS rules, determine the extent to which the University policies contained in this document should be modified, and make recommendations to the University's Chief Academic Officer and President.]

APPENDIX ITEM I:

Significant Financial Interest Disclosure Form And Policy Summary

Investigator Financial Disclosure Policy

(Applicable to all Sponsored Project Proposals <u>except</u> those being submitted to NIH and other US Public Health Service entitles on or after August 24, 2012.)

What is required?

Federal regulations require institutions to have policies and procedures in place that ensure that investigators disclose any significant financial interest that may present a conflict of interest in relationship to externally sponsored projects. Such disclosures must be made prior to the submission of a proposal for funding* and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to award or acceptance of an award.

*If a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required.

Who is covered?

Investigator means the principal investigator/project director, co-principal investigators, and any other person at the University who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term *investigator* includes the investigator's spouse and dependent children.

What must be disclosed?

Each investigator shall disclose all *significant financial interests*:

- (1) That would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor.
- (2) In entities whose financial interests would reasonably appear to be affected by such activities.

What is covered?

Significant financial interests 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 other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term **does not include:**

- (1) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- (2) Income 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 management of those investments.
- (4) Royalties paid by the University.
- (5) Regular salary, summer salary, or overload compensation paid by the University at rates set by the University.
- (6) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: **does not exceed \$10,000** in value as determined through reference to public prices or other reasonable measures of fair market value, or, constitute more than a five percent ownership interest in any single entity.
- (7) 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 \$10,000, and over the next twelve months are not expected to exceed \$10,000.

Disclosure Procedures:

- (1) All Investigators must disclose their significant financial interests utilizing this form and attaching all required supporting documentation. The completed form and packet must be submitted with the proposal using PARS to the Office of Research and Sponsored Programs.
- (2) In the proposal text, or in an attachment to the proposal, the Principle Investigator must describe the conflict of interest or potential conflict of interest. (See Appendix Item II for an example.)
- (3) In accordance with Federal regulations, a complete disclosure must be made by the investigator(s) *prior to submission of the proposal*.
- (4) Steps to manage or eliminate conflicts of interest will be incorporated in a Conflict Resolution Plan approved by the Financial Disclosure Review Committee. Each Investigator must certify that he or she will adhere to all terms and conditions of a Conflict Resolution Plan prior to the University's acceptance of an award.

These forms are available in the Office of Research and Sponsored Programs, Corbett Hall, 581-1472.

Financial Disclosure Review Committee

Michael Eckardt, Chair (VPR) Michael Hastings (ORSP) Jake Ward (DIC) Chair, Research and Scholarship Committee, Faculty Senate Administrative Support – Lynne Crawford

Richard Borgman (BPPH)
James Dill (Cooperative Extension)
Craig Mason (EHD)
Robert Lad (LAS)
David Neivandt (E)
John Singer (NSFA)

APPENDIX ITEM II

The following is a one paragraph example of a conflict of interest description that could be inserted into a proposal narrative.

"Financial Disclosure

The University of Maine is the owner of patents developed by Professor Hugh X.Warren and other University of Maine inventors. The patents will be further explored (or developed, as the case may be, according to the research scope of work) as part of the research contemplated in this proposal. The University of Maine, Professor Warren, and the other inventors have equity interests in the licensee of these patents, QUIET ENERGY, LLC. Professor Warren and the other University-based inventors have developed, or are developing, Conflict of Interest Mitigation plans that manage, eliminate or reduce the conflict. These plans are monitored by the University's Vice President for Research."

APPENDIX ITEM III

[The following is a form for disclosing information relating to conflicts of interest and potential conflicts of interest to the National Institutes of Health and other U.S. Public Health Service entities.]

CONFIDENTIAL

A. IDENTIFICATION OF POSSIBLE CONFLICT OF INTEREST

In the space below, please describe the relevant research activities that may be affected by the financial or ownership interest that you, your spouse, domestic partner, your dependent children, or other household members may have. Complete the remainder of this section with this possible conflict of interest in mind.

Please insert additional pages as necessary to complete this section.

B. OWNERSHIP INTERESTS

List any corporation, partnership, proprietorship, trust, joint venture, and any other business interest, including land used for income in which either you or other members of your household own or have owned within the preceding 12 months that constitute a legal or equitable interest exceeding \$5,000 or five percent of total ownership, whichever is less, which actually or potentially influences or conflicts with any of your research at the University. Ownership of intellectual property, e.g., patents, royalties, and copyrights, is also included and must be disclosed. If you or member(s) of your household own more than five percent of the total ownership interests of a business, you must disclose the percentage held.

Please insert additional pages as necessary to complete this section.
If you have nothing to report in this section, check here

Business Name and Address	Type of Business	Description of Interest	Held by (you/spouse/others)	% Interest Held

C. RECEIPT OF COMPENSATION

List all places of employment and other business (excluding the University) from which you or any member of your household expect to receive \$5,000 or more in remuneration per year as to which an independent observer could reasonably conclude could **actually or potentially influence or conflict with any of your research activities** at the University. Consulting fees, honoraria, paid authorship; 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 are considered, for purposes of this policy, remuneration.

Please insert additional pages as necessary to complete	this section.
If you have nothing to report in this section, check here _	

Business Name and Address	Position Held	Position Held by (You/Spouse/Other)

D. OFFICER OR DIRECTOR OF ORGANIZATION OR BUSINESS

List any organization or business in which you, your spouse, or any other member of your household, hold the position of officer, director, partner, or proprietor for which more than an

aggregate of \$5,000 in compensation is received per year or more than five percent ownership interest is held which significantly affects or will be affected by any of your research activities for the University.

Please insert additional pages as necessary to complete this	section.
If you have nothing to report in this section, check here	

Business Name and Address	Position Held	Position Held by (You/Spouse/Other)

E. RECEIPT OF FEES AND COMMISSIONS

List each client or customer from whom you, your spouse, or any household member receives an aggregate of \$5,000 or more per year which could constitute an **actual or potential conflict of interest with any of your research activities** with the University. In the case of a partnership, it is the proportionate share of the fee or commission that is significant, without regard to the expenses of the partnership. An individual who receives a salary as opposed to portions of fees or commissions is generally not required to report in this section, but may be required to report in Section C, above.

Please insert additional pages as necessary to complete this section	٦.
If you have nothing to report in this section, check here	

Business Name and Address	Position Held	Position Held by (You/Spouse/Other)

F. TRAVEL

Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities. You are NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

Purpose of trip	Sponsor/organizer	Destination, and Duration

CONFIDENTIAL

Section 2 –Declaration	
I,, hereby declare that the interests (including accompanying additional pages and me and that to the best of my knowledge and belief is a statement of all such interests required to be disclosed read and agree to comply with the University of Mac Conflicts of Interest. I have complied with Federal conflicts, I understand that failure to file this statement as statement may result in disciplinary action. Any changes this statement will be reported when it becomes known to	d statements) has been examined by a true, correct, accurate, and complete d by law, regulation, or policy. I have hine System and UMaine policies on lict of interest policies and regulations. I required or intentionally filing a false with regard to information provided on
Signature	Date
Submit this form to your immediate supervisor (Cha and signature.	ir, Director, or Unit Head) for review
VERIFICATION: I have reviewed the potential or actunamed individual. A copy of the signed Significant Finabe/has been sent to the UMaine Conflict of Interest Research for resolution.	ancial Disclosure of Interest Form will
Chair/Director/Unit Head Signature	Date