

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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Procedure Title:	Financial Conflicts of Interest

1.0 Objective

- 1.1. This policy is guided by Code of Federal Regulations (Title 42 CFR Part 50, Subpart F and Title 45 CFR Part 94) that promotes “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator.” The following sections detail the content and implementation of the Policy on *Financial Conflict of Interest (FCOI) Objectivity in Research* at the University of Southern Maine (USM). The policy applies to academic appointees and other persons who are responsible for the design, conduct or reporting of **research, including externally funded projects with primarily educational or service activities.**

- 1.2. The basic principle guiding this policy is the obligation of USM to conduct its research and related academic activities in an ethical manner. Therefore, possible financial conflicts of interest (FCOI) will be disclosed and managed to reduce or dispel any perception of lack of objectivity on the part of our Investigators. At a time when university research activities are becoming more complex and collaborative and relationships with the private sector are strongly encouraged, Investigators face additional challenges in maintaining objectivity and the appearance of objectivity in research. This process is intended to protect Investigators and preserve the credibility of USM through a transparent procedure for conflict disclosure and resolution.

- 1.3. Although this policy pertains to financial conflicts of interest within externally funded research, Investigators are encouraged for their own protection and that of the university to disclose potential conflicts of interest that may appear to bias any research under their influence regardless of funding.

2.0 General Description

- 2.1. Externally funded Investigators shall disclose all potential financial conflicts of interest (FCOI) reasonably related with their research by online submission form at least annually or when there is a significant change. Investigators are also required to complete Collaborative Institutional Training Initiative (CITI) training on FCOI every four years.

3.0 Definitions

- 3.1. **Financial Conflict of Interest (FCOI)** means a situation that creates perceived or actual tensions between personal financial gain and adherence to the fundamental values of honesty, accuracy, efficiency, and objectivity.
- 3.2. **Investigator** means the project director or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, funded by an external entity or proposed for such funding, which may include, for example, collaborators or consultants.
- 3.3. **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.4. **PHS** is Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.
- 3.5. **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 CFR 50, Subpart F or 45 CFR 94.
- 3.6. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.
- 3.7. **“Significant Financial Interest”** means:
 - 3.7.1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse, domestic partners, dependent children, other household members) that reasonably appears to be related to the Investigator’s institutional responsibilities:
 - 3.7.1.1. With regard to any 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 and the value of any equity interest in the entity as of the date of disclosure, when aggregated,

exceeds \$5,000 or five percent of ownership interest in any single entity, whichever is less. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., 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;

- 3.7.1.2. 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 the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- 3.7.1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.7.2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel meeting all of the following criteria:

- 3.7.2.1. The travel is related to the Investigator's institutional responsibilities; and
- 3.7.2.2. The travel is reimbursed or sponsored by someone other than 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.
- 3.7.2.3. Examples of significant financial interests related to travel that must be disclosed include:
 - 3.7.2.3.1. If a company pays for or reimburses an investigator to travel to a professional society meeting;
 - 3.7.2.3.2. If a professional society pays for or reimburses travel to its annual meeting; and/or
 - 3.7.2.3.3. Travel that is paid for or reimbursed by a research sponsor must be disclosed if the investigator is paid directly or reimbursed personally by the sponsor, unless the travel is paid from an institutional account, such as a sponsored project budget.
- 3.7.2.4. Sponsored travel is considered travel paid on behalf of the Investigator and not reimbursed to the Investigator so that its exact monetary value is not readily available.
 - 3.7.2.4.1. Investigator or Senior/Key Personnel are required to disclose the occurrence of any reimbursed or sponsored travel, related to the Investigator or Senior/Key Personnel's institutional responsibilities. Investigator or Senior/Key Personnel only

need to disclose the occurrence of any reimbursed or sponsored travel meeting the following criteria:

- 3.7.2.4.1.1. The travel is related to the Investigator or Senior/Key Personnel's institutional responsibilities; and
- 3.7.2.4.1.2. The travel is reimbursed or sponsored by someone other than a Federal, state, or local government agency, an institution of higher education¹, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- 3.7.2.4.2. At a minimum travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
- 3.7.2.5. The term *significant financial interest* **does not** include the following types of financial interests:
 - 3.7.2.5.1. salary, royalties, or other remuneration paid by USM to the Investigator if the Investigator is currently employed or otherwise appointed by USM, including intellectual property rights assigned to USM and agreements to share in royalties related to such rights;
 - 3.7.2.5.2. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - 3.7.2.5.3. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, such as USM, 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;
 - 3.7.2.5.4. or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, such as USM, 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.

4.0 Responsibility

- 4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), principal investigators and research staff to execute this SOP.

5.0 Procedure

- 5.1. Disclosure upon submission of Intent to Propose (ITP). When submitting an Intent to Propose (ITP) form to the Research Service Center, Investigators are required to disclose potential significant financial conflict of interests. The ITP will ask the Investigator if they have a Disclosure of Financial Interests Form filed with the Office of Research Integrity and Outreach (ORIO), and reviewed and updated within the last twelve (12) months. The ITP will also ask if the Investigator has completed a Financial Conflict of Interest training within the last four years. If the Investigator indicates “no” to either of these questions, they will be required to complete a *Disclosure of Financial Interests Form* and/or training before submission. Completed Disclosure of Financial Interests Form should be submitted to ORIO. ORIO will document receipt of the form and send a duplicate to Human Resources.
- 5.2. Disclosure upon change in financial interests. If an Investigator’s financial status changes (e.g. through purchase, marriage, or inheritance) creating a new or potential significant financial interest which an independent observer could reasonably conclude may be related with any of the Investigator’s research at USM, the Investigator must submit a completed *Disclosure of Financial Interests Form* to ORIO within thirty (30) days. ORIO will document receipt of the form and send a duplicate to Human Resources.
- 5.3. Annual updated disclosure in financial interests. After the initial submission, Investigators participating in externally funded research will submit *Disclosure of Financial Interests Form* annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to USM pursuant to paragraph 5.a of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a externally funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- 5.4. Review of disclosures. The Research Integrity Officer, or their designees as appropriate, will review Financial Disclosure Forms upon proposal submission. For those situations in which there is no potential FCOI, the designated reviewer signs to confirm review. For those cases in which there is a potential FCOI, the submitted Financial Disclosure Form is referred by the Research Integrity Officer to the USM Committee on Financial Conflict of Interests (through the committee chair or convener) for review and management.
- 5.5. Organizational conflicts of interest and human research protections. When an organizational conflict of interest exists in human subject research, the Research Compliance Administrator (RCA) will work closely with the IRB Chair to determine if the conflict could affect the rights and welfare of subjects participating in the project, the integrity of data collected, or objectivity by which the human research protocol is managed. (See *HRPP-023 IRB Member IRB Staff and Organizational Conflicts of*

Interest)

5.5.1. If the RCA and IRB Chair determine that an organizational conflict of interest could affect the rights and welfare of participants, the integrity of data collected, or objectivity by which the human research protocol is managed, then the conflict of interest must be eliminated or a management plan implemented so that the rights and welfare of participants and integrity of the research projects are not affected by the interest.

5.5.2. Details of organizational financial conflicts will be reported in the IRB minutes, including details of deliberations related to the conflicting interest.

5.6. Management of Conflicting Interests.

5.6.1. Committee. The Committee on Financial Conflicts of Interest is a standing committee. The Committee will have a minimum of four (4) members appointed by the Provost with the following representation:

5.6.1.1. One (1) Research Council representative;

5.6.1.2. One (1) Research Service Center representative;

5.6.1.3. One (1) member from Human Resources;

5.6.1.4. The Research Integrity Officer will be a non-voting ex officio member.

5.6.2. Committee responsibilities. The responsibilities of the Committee, relative to financial conflicts of interest, will be to receive disclosures with potential FCOI, and to review these disclosures in a face-to-face meeting of a quorum of the Committee within thirty (30) days of receiving the disclosure. Prior to the expenditure of any funds under the research project, the Committee will make a determination as to whether there is reasonable expectation that a significant financial interest could affect the research or is in an entity whose financial interest could be affected by the research. If there is such an expectation, the Committee will then determine whether the significant financial interest could directly and significantly affect the design, conduct or reporting of the research and is, therefore, a FCOI. By written or electronic memo, the Committee chair will inform the President, Provost, and cognate department head/chair or supervisor of the Committee's opinion regarding the FCOI. The memo will include recommendations on management, reduction or elimination of the conflict of interest. The Provost will accept or modify the recommendations, and communicate the decision and any required actions in writing to the Investigator.

5.6.3. Recommendations for management, reduction or elimination of the conflict of interest. Prior to the expenditure of any funds under the research project, the Committee will implement a management plan that shall specify the actions taken or to be taken to manage an identified FCOI. The management plan may include

but is not limited to measures such as:

- 5.6.3.1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - 5.6.3.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 5.6.3.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
 - 5.6.3.4. Modification of the research plan;
 - 5.6.3.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 5.6.3.6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - 5.6.3.7. Severance of relationships that create financial conflicts.
- 5.6.4. For research projects involving human subjects research, the Research Integrity Officer will inform the RCA and the IRB chair of the management plan.
- 5.6.4.1. If the IRB determines that the proposed financial conflict of interest management plan is insufficient as drafted, the IRB will revise the management plan to ensure the rights and welfare of participants and integrity of the research project is not affected by the interest.
 - 5.6.4.2. The revised management plan will be shared with The Committee on Financial Conflicts of Interest.
 - 5.6.4.3. The IRB has the final authority to decide whether the conflict of interest and its management, if any, allows the research to be approved.
- 5.6.5. Appeal of resolution decisions and final authority. Investigators may appeal the resolution in writing to the President within ten (10) days of receiving written notice of the Committee's decision. The appeal is confined to presenting new information about the financial interest or a viable resolution procedure that was not previously discussed. The President shall meet with the Committee chair, other Committee members as appropriate, and either accept or decline the appeal in writing to the Investigator within ten (10) days. If the appeal is accepted, a revised strategy for FCOI management, reduction or elimination will be provided to the Investigator in writing. A declined appeal is final.
- 5.6.6. Continuing review. Strategies for managing FCOI will include specified periods for continuing review, identify the person(s) responsible for conducting and reporting on reviews, and establish the authority to enforce management mechanisms and sanctions. The Committee will monitor any implemented management plan on an ongoing basis for compliance until the completion of the research project.

6.0 Reporting conflicts of interest

- 6.1.** Prior to the expenditure of any funds under an award, USM will report to the funding agency the existence of a FCOI found and assure that the conflict has been managed, reduced, or eliminated. When the research project involves Public Health Service (PHS) funds the reporting requirements will be in accordance with 42 CFR 50 Subpart F and 45 CFR 94. Any FCOI identified subsequently will be reported and managed, reduced, or eliminated within sixty (60) days of identification. To the extent required by law, USM will make available to the appropriate governmental agencies, upon request, information regarding all identified FCOI and their management, reduction, or elimination. If the Investigator has biased the research, USM will promptly notify the funding agency (in the case of PHS, the PHS awarding component) of the corrective action taken or to be taken.

- 6.2.** Discovery of an undisclosed significant financial interest. Whenever USM identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by USM during an ongoing funded research project (e.g., was not timely reviewed or reported by a sub recipient), the Committee on Financial Conflicts of Interest shall, within 60 sixty days: review the significant financial interest; determine whether it is related to funded research; determine whether a financial conflict of interest exists; and, if so:
 - 6.2.1.** Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

 - 6.2.2.** In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by USM to constitute a FCOI; failure by USM to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, USM shall, within one hundred twenty (120) days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. USM will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
 - 6.2.2.1.** Project number;
 - 6.2.2.2.** Project title;
 - 6.2.2.3.** Project Director (PD)/Principal Investigator (PI) or contact PD/PI if a multiple PD/PI model is used;
 - 6.2.2.4.** Name of the Investigator with the FCOI;
 - 6.2.2.5.** Name of the entity with which the Investigator has a FCOI;

- 6.2.2.6. Reason(s) for the retrospective review;
- 6.2.2.7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- 6.2.2.8. Findings of the review; and
- 6.2.2.9. Conclusions of the review.

6.3. If a FCOI involves **PHS-funded** research, based on the results of the retrospective review, USM shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, USM will notify the relevant funding agency promptly and submit a mitigation report to the PHS awarding component when required. The mitigation report will 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 USM'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). USM will submit FCOI reports annually as required under 42 CFR 50 Subpart F and 45 CFR 94. Depending on the nature of the FCOI, USM may determine that additional interim measures are necessary with regard to the Investigator's participation in the externally funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

6.4. New Investigator with a significant financial interest. Whenever, in the course of an ongoing externally funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to USM, the designated official(s) shall, within sixty (60) days:

6.4.1. review the disclosure of the significant financial interest;

6.4.2. determine whether it is related to PHS-funded research;

6.4.3. determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

6.5. Depending on the nature of the significant financial interest, USM may determine that additional interim measures are necessary with regard to the Investigator's participation in the externally funded research project between the date of disclosure and the completion of the review.

7.0 Disciplinary Action

- 7.1. Discovery of a previously undisclosed FCOI will require review by the Committee on Financial Conflicts of Interest in accordance with the procedure set forth in paragraphs 5 and 6 of this policy, and 42 CFR 50, Subpart F and 45 CFR 94 when applicable. If it is determined that a significant financial interest exists that would potentially be considered insubordination or other actionable offense, the matter will be referred to Human Resources to handle in accordance with USM progressive disciplinary practices and as spelled out in any contractual language.
- 7.2. When Investigators fail to file a statement as required by this policy, the matter will be referred to Human Resources to handle in accordance with USM progressive disciplinary practices and as spelled out in any contractual language.

8.0 Public Accessibility

- 8.1. This policy will be kept up-to-date, enforced and in compliance with 42 CFR 50, Subpart F and 45 CFR 94.
- 8.2. This policy and information on FCOIs will be made available via the ORIO website: <https://usm.maine.edu/orio/financial-conflicts-interest>.
- 8.3. For **PHS-funded** research, USM shall ensure public accessibility by written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to USM that meets the following three criteria:
 - 8.3.1. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by 42 CFR 50, Subpart F and
 - 8.3.2. 45 CFR 94 and USM policy;
 - 8.3.3. USM determines that the significant financial interest is related to the **PHS-funded research**; and
 - 8.3.4. USM determines that the significant financial interest is a FCOI.
- 8.4. The information USM makes available via written response to any requestor within five (5) business days of a request, shall include, at a minimum, the following:
 - 8.4.1. the Investigator's name;
 - 8.4.2. the Investigator's title and role with respect to the research project;
 - 8.4.3. the name of the entity in which the significant financial interest is held;

- 8.4.4. the nature of the significant financial interest;
 - 8.4.5. and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- 8.5.** USM will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of the USM’s identification of a new FCOI, which should be requested subsequently by the requestor.
- 8.6.** Information concerning the significant financial interests of an individual determined to be a FCOI under this policy shall remain available, for responses to written requests for at least five (5) years from the date that the information was most recently updated.

9.0 Training

- 9.1.** Each externally funded Investigator will be informed of the USM FCOI policy, the Investigator’s responsibilities regarding disclosure of significant financial interests, the applicable regulations, and is required to complete training regarding the same prior to engaging in research related to any externally funded project and at least every four years thereafter, and **immediately** when any of the following circumstances apply:
- 9.1.1. USM revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - 9.1.2. An Investigator is new to USM; or
 - 9.1.3. It is determined that an Investigator is not in compliance with USM’s FCOI policy or management plan.
- 9.2.** Investigators are expected to complete the FCOI training prior to engaging in externally funded research or by the issue date of the Notice of Award issue by the funding agency.
- 9.3.** “Immediately” for the purposes of this section means a reasonable timeframe of no more than thirty (30) business days.

10.0 Drugs, medical devices, and treatments

- 10.1** If a **PHS-funded** project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or

reported by an Investigator with a conflicting interest that was not disclosed or managed as required by 42 CFR 50 Subpart F or 45 CFR 94, USM requires that the Investigator(s) involved disclose the conflicting interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

11.0 Recordkeeping

11.1. Records will be kept in Human Resources in the appropriate personnel files and with ORIO for a minimum of five (5) years following the date of submission of the final expenditures report to the external funding agency.

12.0 Sub recipient Institutions/Investigators and Reporting of identified FCOIs

12.1. When USM carries out PHS funded research through a subrecipient (*e.g.*, subcontractors, or consortium members), USM will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50, Subpart F and 45 CFR 94 by:

12.1.1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of USM or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of USM for disclosing significant financial interests that are directly related to the sub recipient's work for USM;

12.1.2. Additionally, if the sub recipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to USM. Such time period(s) shall be sufficient to enable USM to provide timely Financial Conflict of Interest (FCOI) reports, as necessary, to the PHS as required by 42 CFR Part 50, Subpart F and 45 CFR 94;

12.1.3. Alternatively, if the sub recipient's Investigators must comply with USM's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to USM. Such time period(s) shall be sufficient to enable USM to comply timely with its review, management, and reporting obligations under 42 CFR Part 50, Subpart F and 45 CFR 94;

12.1.4. Providing FCOI reports to the PHS Awarding Component, when applicable, regarding all FCOI of all subrecipient Investigators consistent with 42 CFR Part 50, Subpart F and 45 CFR 94, *i.e.*, prior to the expenditure of funds and within

sixty 60 days of any subsequently identified FCOI.

13.0 References

13.1. Title 42 CFR Part 50, Subpart F Title 45 CFR Part 94b

13.2. NSF 05-131 July 2005 Chapter V - Grantee Standards section 510 Conflict of Interest Policies

13.3. University of Maine System Policy Section 410 Conflict of Interest