University of Southern Maine
Financial Conflicts of Interest FAQ’s

Below please find a list of Financial Conflict of Interest FAQ’s. If your questions are not answered here please feel free to contact us directly. We can be reached via email at usmorio@usm.maine.edu or by phone at 207-780-4517. We are happy to help!

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1. What is the purpose of this Financial Conflicts of Interest (the FCOI) Policy?

- To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under external funding will be free from bias resulting from Investigator financial conflicts of interest (FCOI).
2. **What is a “Financial Conflict of Interest”?**

- A situation that creates perceived or actual tensions between personal financial gain and adherence to the fundamental values of honesty, accuracy, efficiency, and objectivity.
- A FCOI occurs when the University of Southern Maine (USM) reasonably determines that an investigator’s significant financial interest is related to an externally funded research project and could directly and significantly affect the design, conduct or reporting of the externally funded research.

3. **What is covered by the FCOI Policy?**

- The FCOI Policy only applies to research performed under external funding, such as a grant or cooperative agreement, with a Notice of Award issue date (including noncompeting continuations) that is after 8/17/2012.

4. **Does the FCOI Policy apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)?**

- Yes. The FCOI Policy is applicable to each investigator planning to participate in, or participating in externally funded research. A subrecipient relationship is established when federal funds flow down from or through USM as an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. The awardee institution is required to incorporate as part of a written agreement with the subrecipient terms that establish whether the FCOI Policy of the awardee Institution or that of the subrecipient apply to the subrecipient’s Investigators. Please consult the Office of Research Integrity and Outreach (ORIO) to determine which FCOI Policy applies.

5. **I am a collaborator/consultant/subgrantee/subcontractor/subrecipient performing externally funded research but am not employed directly by USM. Does this still regulation apply to me?**

- Yes. If you meet the definition of an “Investigator (defined below),” the FCOI Policy applies to you.

6. **I am a doctoral or graduate student receiving external funding. Does this FCOI Policy apply to me?**

- Yes. If you meet the definition of an “Investigator,” the FCOI Policy applies to you.

7. **Who are the “senior/key personnel” in externally funded research?**

- “Senior/Key Personnel” means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by USM in the grant application, progress report, or any other report submitted to the funding source.
8. **Who is considered an “Investigator”?**

- “Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the externally funded research, or proposed for such funding, which may include, for example, collaborators or consultants. In addition, the Investigator must also disclose Significant Financial Interests of his/her spouse and dependent children.

9. **What are “institutional responsibilities”?**

- “Institutional responsibilities” are defined as the Investigator’s professional responsibilities on behalf of USM.

10. **What does “prior to the Institution's expenditure of any funds” mean as provided in the FCOI Policy?**

- After the funding source issues a grant or cooperative agreement award, “prior to the Institution's expenditure of any funds” is the period of time before an expense is recorded in the official records of USM.

11. **Do Investigators need to disclose salary paid by USM?**

- No.

12. **Do I need to disclose the occurrence of any reimbursed or sponsored travel related to my institutional responsibilities?**

- Yes. The FCOI Policy requires Investigators to disclose the occurrence of any reimbursed or sponsored travel, related to the Investigator’s institutional responsibilities. Investigators only need to disclose the occurrence of any reimbursed or sponsored travel meeting the following criteria:
  - i. The travel is related to the Investigator’s institutional responsibilities and
  - ii. 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.

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¹ “Institution of higher education” means an educational institution in any State that - (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate; (2) is legally authorized within such State to provide a program of education beyond secondary education; (3) provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree; (4) is a public or other nonprofit institution; and (5) is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted preaccreditation status by such an agency or association that has been recognized by the Secretary for the granting of preaccreditation status, and the Secretary has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.
• Examples of significant financial interests related to travel that **must be disclosed** include:
  i. If a company other than those listed in #2 above pays for or reimburses an investigator to travel to a professional society meeting.
  ii. If a professional society pays for or reimburses travel to its annual meeting.
  iii. 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.

13. **Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)?**

• Yes. The FCOI Policy does not provide a *de minimis* threshold for the disclosure of reimbursed or sponsored travel. The FCOI Policy requires disclosure of basic information about such travel including at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. However, the investigator does not need to disclose the dollar amount. USM will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the externally funded research.

• Travel to scientific meetings and to present Investigator’s research to colleagues and other interested parties is an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers. The FCOI Policy is not intended to discourage this type of travel but require the disclosure of the occurrence of any reimbursed or sponsored travel related to the Investigator’s institutional responsibilities.

14. **Does the FCOI Policy require Investigator training?**

• Yes, after **August 17, 2012** each Investigator, including subrecipient Investigator(s), must complete the CITI, online FCOI module prior to engaging in externally funded research and at least every four years, and immediately (as soon as possible, but not later than ten (30) working days) under the below circumstances:
  i. The USM FCOI Policy changes in a manner that affects training requirements;
  ii. An Investigator is new to USM;
  iii. USM finds that an Investigator is not in compliance with USM’s FCOI Policy or management plan additional specific training will be required.

15. **Which form do I fill out?**

• **Disclosure of Financial Interests Form A** submitted initially for all active external awards.
• **Disclosure of Financial Interests Form B** submitted annually after initial Form A to disclose whether there are any changes or not.
### Investigator SFI Disclosure and Institutional FCOI Reporting Requirements

<table>
<thead>
<tr>
<th>Investigator Discloses known SFI(s) to the Institution</th>
<th>Institution Reports identified FCOI(s) to the NIH (Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH.)</th>
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</thead>
<tbody>
<tr>
<td>At time of Application</td>
<td>Prior to the Expenditure of Funds</td>
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<tr>
<td>Within 30 days of acquiring or discovering SFI</td>
<td>Within 60 days of identification</td>
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<td>Annually at the time period prescribed by the Institution during the award period</td>
<td>Annually: At the same time as when the grantee is required to submit the annual progress report, including multi-year progress report, or at time of extension. Annual FCOI report is submitted through eRA Commons FCOI Module.</td>
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### Summary of FCOI Noncompliance

**FCOI REPORT (within 60 days)**
- Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

**RETROSPECTIVE REVIEW (to determine bias)**
- If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

**UPDATE/REVISE FCOI REPORT (following retrospective review)**
- If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward.

**MITIGATION REPORT (promptly after retrospective review)**
- If bias is found, notify NIH promptly
- Submit mitigation report through FCOI Module

**ANNUAL FCOI REPORT**
- Submit annual FCOI report thereafter through FCOI Module