

Oregon Museum of Science and Industry Policy and Procedures on Financial Conflict of Interest Related to Federally Sponsored Projects

Policy

Whenever an investigator has a significant financial interest in an enterprise which might reasonably appear to be affected by discoveries in the investigator's sponsored project, there is the potential for a real or perceived conflict of interest. Although the Oregon Museum of Science and Industry (OMSI) does not require investigators to disclose their personal financial interests as a matter of routine, OMSI is sometimes obligated to require disclosure under federal regulations. Such disclosures are the most widely accepted method for identifying and managing actual or potential financial conflicts of interest related to federally sponsored projects.

It is the policy of OMSI that all investigators (including sub-recipients, collaborators, and consultants) on federally sponsored projects are required to disclose all significant financial interests (and those of the investigator's spouse and dependent children) that are related to their institutional responsibilities. When OMSI determines that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, OMSI will take steps to manage the conflict.

This policy implements federal requirements pertaining to U.S. Public Health Service (PHS), which includes National Institutes of Health (NIH), and which are published in 42 CFR Part 50. This policy also implements federal requirements contained in the National Science Foundation Award and Administration Guide's "Conflict of Interest Policies." Both agencies require OMSI maintains an appropriate written policy on conflict of interest disclosure as a condition for receiving their grants. These requirements, as implemented in this policy, are applicable to all proposals and awards for federally sponsored projects at OMSI.

Definitions

Institutional Responsibilities

Institutional responsibilities are defined as an Investigator's professional responsibilities on behalf of OMSI, and may include activities such as research, research consultation, teaching, professional practice and OMSI committee memberships.

Investigator

Investigator is defined as 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 research and projects funded by federal awards or proposed for such funding, which may include, for example, subrecipients, collaborators or consultants.

OMSI Reviewing Official

An official designated by OMSI to collect and review completed Financial Interest Disclosure Forms and to make the initial determination whether any reported financial interest would reasonably appear to directly and significantly affect the design, conduct or reporting of the sponsored project. The OMSI Reviewing Official is currently the Senior Director of Institutional Giving.

Significant Financial Interest

A financial interest must be reported when required by the above-referenced federal regulations. The requirement that an Investigator must report a Significant Financial Interest under the terms of this policy does not in and of itself imply the existence of an actual or potential conflict of interest. The existence of a conflict of interest is determined subsequently by the designated OMSI Reviewing Official, the Vice President with oversight of the project, and, when necessary, review committee. If a conflict is identified, additional steps to manage the conflict may be required.

Consistent with current federal regulations, OMSI identifies two sets of definitions of Significant Financial Interest, one applicable to all federally-funded project proposals and awards except for those funded by PHS, and the other applicable only to PHS-funded project proposals and awards. This policy defines Significant Financial Interest as anything of monetary value, including, but not limited to:

All federal project funding except for PHS:

1. Income from a single business entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value, exceeding \$10,000 during the prior twelve months when aggregated for an Investigator, Investigator's spouse/domestic partner and dependent children;
2. Income from a single public or nonprofit entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity or any other payments or consideration with value, exceeding \$10,000 during the prior twelve months when aggregated for an Investigator, Investigator's spouse/domestic partner and dependent children, excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for public or non-profit entities;
3. An equity interest, in the form of stock, stock options, real estate, or any other investment or ownership interest, a 5% ownership interest, or a loan to the entity, exceeding \$10,000 in value, for any one enterprise when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children;
4. A management position such as board member, director, officer, partner, or trustee, held by the Investigator; or
5. Intellectual property interest held by the Investigator or Investigator's spouse/domestic partner or dependent children on a patent, patent application,

or a copyright of software that would reasonably appear to be affected by the sponsored project at issue.

PHS project funding:

a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) 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. 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;

(ii) 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/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. A \$5,000 threshold applies to income received related to intellectual property rights and interests, royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights.

b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel above the \$5,000 annual threshold (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to 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.

In all cases, the term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by OMSI to the Investigator if the Investigator is currently employed or otherwise appointed by OMSI, including intellectual property rights assigned to OMSI and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or

teaching engagements 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; or income from service on advisory committees or review panels for 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.

Investigator Responsibilities

All Investigators on proposed or funded federally supported projects are required to become familiar with the current OMSI policy and procedures for managing conflicts of interest (this document), and to distribute copies of the policy and procedures to all individuals who will participate as Investigators on the federally supported project.

The federal regulations require that Investigators submit to the OMSI Reviewing Official all Significant Financial Interests in advance of submission of the application to the agency. Specifically, an Investigator must disclose all Significant Financial Interests (and those of their spouse and dependent children) that are related to their institutional responsibilities. .

OMSI Reviewing Official Responsibilities

[It is the responsibility of the OMSI Reviewing Official to determine if the Significant Financial Interest is related to the research or project. The OMSI Reviewing Official can consult with the Investigator in making this determination. If the Significant Financial Interest is related to the research or project, the OMSI Reviewing Official then asks the following questions: 1) Could the Significant Financial Interest be affected by the research or project? 2) Is the Significant Financial Interest in an entity whose financial interest could be affected by the research or project? If the Significant Financial Interest is related to the research or project and if the answer is yes to either of these two questions, then a financial conflict of interest exists and will be managed and reported to the NIH via the eRA Commons FCOI Module.]

To comply with federal regulations, OMSI will require the following actions from Investigators on federally funded projects:

- An Investigator with no Significant Financial Interest to disclose must so certify by signing the annual Financial Interest Disclosure Form.
- An Investigator with Significant Financial Interests must submit a Financial Interest Disclosure Form to the OMSI Reviewing Official prior to proposal submission.
- Within 30 days of discovering or acquiring a new reportable Significant Financial Interest, submission of a Financial Interest Disclosure Form to the OMSI Reviewing Official is required from all Investigators with current awards or pending applications for federally funded projects.

- Completion of a Financial Interest Disclosure Form will be required at the beginning of the calendar year from all Investigators with current awards.

Additional Investigator Responsibilities under PHS-funded Projects

- PHS-funded Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities (that is above the \$5,000 annual threshold), as defined above. The disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The OMSI Reviewing Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Significant Financial Interest with the PHS-funded project.
- PHS-funded Investigators (including subrecipient Investigators) must complete training on Financial Conflicts of Interest prior to engaging in research related to a PHS-funded project and at least every four years thereafter, and immediately under any of the following circumstances:
 - OMSI Financial Conflict of Interest policies change in a manner that affects Investigator requirements;
 - An Investigator is new to OMSI; or
 - OMSI finds that an Investigator is not in compliance with OMSI's Financial Conflict of Interest policy or management plan.
- Investigators may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training. Information on the training requirement will be provided by the OMSI Reviewing Official.

OMSI Responsibilities

OMSI is responsible for monitoring Investigator compliance with a management plan until completion of the federally sponsored project or until the financial conflict of interest no longer exists.

The Investigator will forward the Financial Interest Disclosure Form to the OMSI Reviewing Official, who will review it and confer with the responsible Vice President as appropriate. Disclosures that in the opinion of the responsible Vice President need the review of an ad hoc committee will be referred to a committee appointed by the Vice President; composition of the committee will be determined by the Vice President, and will typically include both scientists or educators and administrators. An Investigator who desires to have his/her own disclosure reviewed by the committee may so inform the OMSI Reviewing Official, for referral to the responsible Vice President. Investigators may also elect to have the committee review other financial interests not related to federally sponsored projects covered by this policy (in which case the portion of the policy regarding OMSI's responsibility to report certain circumstances to the funding agency is not applicable). The committee will review disclosures referred to it and

initiate steps to manage potential conflicts in consultation with the responsible Vice President. The information disclosed will be kept confidential to the extent permitted by law.

When an Investigator who is new to participating in the research or project or when an existing Investigator discloses a new Significant Financial Interest, the OMSI Reviewing Official shall within 60 days review disclosures, determine whether the Significant Financial Interest is related to PHS/NIH-funded research or project; determine whether a financial conflict of interest 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 financial conflict of interest.

Additional OMSI Responsibility for Retrospective Review of PHS-funded Projects

If OMSI determines that a financial conflict of interest was not reviewed or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined by OMSI to constitute a financial conflict of interest, or failure by the Investigator to comply with a management plan for a financial conflict of interest, the responsible Vice President and/or their review committee will, within 120 days of a determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded project to determine whether the project (or any portion thereof) conducted during the period of non-compliance was biased in the design, conduct or reporting. OMSI will document the review, develop a plan to manage any identified financial conflict of interest, and notify PHS and submit a mitigation report, as required.

Methods to Manage Conflicts of Interest

The responsible Vice President and/or the review committee is responsible for determining what mechanisms are appropriate for managing, reducing or eliminating real or potential financial conflicts of interest. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate financial conflicts of interest include:

- Public disclosure of financial conflicts of interest. Some examples of public disclosure could include (but are not limited to), when presenting or publishing the research or project; to staff members working on the project; to OMSI's review committee;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research or project against bias resulting from the financial conflict of interest;
- Modification of the research or project plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research or project;
- Elimination of the financial interest; and/or
- Severance of relationships that create actual or potential financial conflicts.

Enforcement Mechanisms

Certain federal regulations require that sanctions for non-compliance be imposed where necessary. Possible sanctions might include a letter of reprimand sent to the Investigator; a requirement for special certifications or assurances of compliance; restrictions on any grant awards involving the Investigator; barring the Investigator from submitting any new proposals through OMSI; suspension; dismissal, or other action as appropriate.

Agency Notifications

All federal funding agencies except for PHS: If a conflict of interest cannot be resolved on a federally-funded project, the appropriate agency official must be so notified. The responsible Vice President will provide appropriate written notice to the agency.

PHS:

(i) Prior to the expenditure of any funds under a PHS award, OMSI must provide to PSH a financial conflict of interest report regarding any Investigator Significant Financial Interest found by OMSI to be a financial conflict of interest in accordance with the regulation. OMSI must also provide a financial conflict of interest report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever OMSI, for whatever reason, does not review a disclosed Significant Financial Interest and OMSI then determines that a financial conflict of interest exists;

(ii) OMSI must submit a financial conflict of interest report within sixty days after its determination that a financial conflict of interest exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to OMSI during the period of award; and

(iii) For any financial conflict of interest previously reported by OMSI, OMSI must provide an annual financial conflict of interest report that addresses the status of the financial interest and any changes to the management plan. Annual financial conflict of interest reports shall specify whether the financial conflict of interest is still being managed or explain why the financial conflict of interest no longer exists. OMSI will submit to PHS annual financial conflict of interest reports (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when OMSI is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of a project extension with or without funds.

All reports submitted will contain all elements required under 42 CFR 50.605.

Records Retention

The OMSI Reviewing Official will maintain records of all Investigator disclosures of financial interests, and OMSI's review of or response to such disclosure (whether or not a disclosure resulted in OMSI's determination of a financial conflict of interest), and all actions under the financial conflict of interest policy or retrospective review, if applicable, for at least 3 years from the date of submission of final expenditure report or, where applicable, from other dates specified in 45 C.F.R. 75.361 (see FAQ A.11) for different situations. .

PHS Subawards, Subcontracts and Collaborators

For all PHS-funded projects carried out through subgrantees, contractors or collaborators (e.g., those persons or institutions conducting a substantive portion of the PHS-funded project, who will design, conduct or report the results of the project, and who are accountable to OMSI for programmatic outcomes and compliance matters), OMSI will ensure that Investigators working for such entities comply with the applicable PHS regulations, either by requiring those Investigators to comply with the OMSI policy or by requiring the entities provide assurances of compliance with applicable PHS regulations.

Public Accessibility

OMSI will post its Policy and Procedures on Financial Conflict of Interest Related to Federally Sponsored Projects on its public website at www.oms.edu. Requests for information on PHS-funded financial conflicts of interest must be directed to the OMSI Reviewing Official; responses to requests will be issued per the PHS regulations at 42 CFR Part 50 within five business days of receipt of the request, concerning any Significant Financial Interest disclosed to OMSI that meets the following three criteria:

1. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the federal-funded research project identified by OMSI in the grant application, progress report, or any other required report submitted to the federal awarding agency;
2. OMSI determines that the Significant Financial Interest is related to the federal-funded research or project; and
3. OMSI determines that the Significant Financial Interest is a Financial Conflict of Interest.