

3.06 SCIENTIST CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT

PART I. INVESTIGATOR SIGNIFICANT FINANCIAL INTEREST DISCLOSURE POLICY

Approved: 09/10/2012

DEFINITIONS

A Financial Conflict of Interest (FCOI) exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse 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 and is related to the Investigator's institutional responsibilities. 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 and is related to the Investigator's institutional responsibilities, 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
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

A potential conflict of interest occurs when an individual has an external interest that affects or provides an incentive to affect the individual's conduct of his or her OSLC activities 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. An actual conflict of interest depends on the situation and not on the character or actions of the individual. The existence of a conflict of interest does not imply wrongdoing; however, conflicts of interest must be recognized, disclosed and either eliminated or properly managed.

Section 3. Funding and Scientific Research

3/24/2021

For purposes of this policy, a conflict of interest exists when OSLC, through procedures described herein, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.

Investigator means the PI/Project Director, Co-I, and any other person 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 his or her spouse and dependent children.

Significant Financial Interest means anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees, paid authorships or honoraria);
- Equity interests (e.g., stocks, stock options, or other ownership interests) and is related to the investigator’s institutional responsibilities;
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

- Salary, royalties, or other remuneration from OSLC;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities. Excluded from disclosure requirement: 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;
- Income from service on advisory committees or review panels for public or nonprofit entities. Excluded from disclosure requirement: Service on advisory 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.
- An equity interest that, when aggregated for the Investigator and his or her spouse and dependent children, meets both of the following tests: Exceeds \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and represents more than a five percent (5%) ownership interest in any single entity and is related to the investigator’s institutional responsibilities. Types of equity interest excluded: Excludes 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;

Salary, royalties, or other payment that, when aggregated for the Investigator and his or her spouse and dependent children over the next twelve (12) months, are expected to exceed \$5,000.

Significant Financial Interests threshold: De minimis threshold of \$5,000 for disclosure generally applies to payments for services and/or equity interests. Includes any equity interest in non-publicly traded entities and is related to the Investigator’s institutional responsibilities.

Travel reimbursements and sponsored travel: Any reimbursed travel or sponsored travel related to OSLC responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Excluded from disclosure requirement: Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution

Section 3. Funding and Scientific Research

3/24/2021

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. OSLC will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

FCOI training: Each Investigator must complete training upon becoming a scientist at OSLC, prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately if OSLC finds an Investigator noncompliant with Institution's FCOI policy or management plan.

Retrospective Review OSLC will conduct a retrospective review in those cases of non-compliance with the regulations. OSLC will notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

Public Accessibility: OSLC will make information available concerning identified FCOIs held by senior/key personnel by a written response to any requestor within five business days of a request and update such information as specified in the rule. This information will include at a minimum the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest, 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.

POLICY

Under the 2011 revised regulation, Investigators are required to disclose their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

1. no later than at the time of application for NIH-funded research;
2. within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
3. at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

PROCEDURES

1. Each Investigator is required to complete a disclosure form (attached) annually, either stating that s/he does not have any Significant Financial Interest to disclose, or disclosing the following:
 - a) Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the research funded, or proposed for funding, by an external sponsor; or
 - b) Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research funded, or proposed for funding, by an external sponsor.
2. To avoid any appearance of a conflict of interest, an Investigator may wish to disclose other interests that could bias the design, conduct, or reporting of research. It is wise to also disclose amounts under \$5,000 if they are from a source that is very pertinent to the Investigator's research. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Section 3. Funding and Scientific Research

3/24/2021

3. Each Investigator shall submit the completed disclosure form and supplemental material to the COO. The COO, along with the President of the Board of Directors and one Board member with expertise in science and/or research, will serve as the Institutional Officials responsible for determining what conditions or restrictions, if any, are required to manage, reduce or eliminate a conflict. The Board member selected shall not be the OSLC scientist or employee Board member.
4. As required by Federal regulation, all Significant Financial Interests that meet the criteria in 1a or 1b must be disclosed prior to the time a grant proposal is submitted. Investigators must update all financial disclosures during the period of the award as new reportable Significant Financial Interests are obtained. When a PI certifies a grant submission, the form will include a check off of whether his/her disclosure form needs to be updated.
5. When submitting a disclosure form that indicates a real or potential conflict of interest, the Investigator shall describe how the relationship represents an conflict and any actions s/he has already taken to manage, reduce, or eliminate the conflict including:
 - a) Public disclosure of Significant Financial Interests;
 - b) Review of research protocol by independent reviewers; and
 - c) Monitoring of research by independent reviewers.
6. The Institutional Officials shall review the disclosure form and determine whether the situation qualifies as a Significant FCOI. If the Institutional Officials determine that the situation does not qualify, they will prepare a summary letter to indicate the information reported has been reviewed and does not qualify as a Significant FCOI. The Board President and COO will sign the letter, and the letter will be held in a confidential file.
7. If the Institutional Officials determine that the information presented in the disclosure form does qualify as a Significant FCOI, the group will ask the Investigator to prepare a proposed Resolution Plan. The Institutional Officials will work with the Investigator to agree to a plan for managing the conflict of interest. Conditions and restrictions may include the following:
 - a) Additional disclosures needed;
 - b) Additional oversight of the research protocols;
 - c) Modification of the research plan;
 - d) Disqualification from participation in all or a portion of the research funded;
 - e) Divestiture of Significant Financial Interests; or
 - f) Severance of relationships that create actual or potential conflicts of interest.
8. OSLC will report to NIH a significant conflict of interest that significantly affects the design, conduct or reporting of NIH funded research. OSLC will report the following:
 - a) The role and principal duties of the conflicted Investigator in the research project;
 - b) Conditions of the management plan;
 - c) How the management plan is designed to safeguard objectivity in the research project;
 - d) Confirmation of the Investigator's agreement to the management plan;
 - e) How the management plan will be monitored to ensure Investigator compliance; and
 - f) Other information as needed.

Updated or annual FCOI reports will include the status of the management plan (i.e., whether the financial conflict is still being managed or an explanation of why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

9. The approved Resolution Plan shall be incorporated into a Memorandum of Understanding between OSLC and the Investigator detailing the conditions or restrictions imposed upon the Investigator in the conduct of the

Section 3. Funding and Scientific Research

3/24/2021

- project or in the relationship with the Business Enterprise or Entity. The Board President and COO will sign the Memorandum of Understanding.
10. Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines and all required reports regarding the conflict of interest will be submitted to the sponsor prior to expenditure of any funds under an award. The PHS requires the Institution to report to the PHS Awarding Component the existence of a conflicting interest found by the Institution (but not the nature of the interest or other details) and assure that the interest has been managed, reduced, or eliminated.
 11. Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest are confidential and shall be retained in sealed envelopes in a secure file kept by the OSLC COO until three (3) years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is later.
 12. Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the Board President shall recommend sanctions which may include disciplinary action ranging from a public letter or reprimand to dismissal and termination of employment.
 13. OSLC shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator, until the matter is resolved.
 14. Investigators are required to declare conflicts of interest in publications and presentations of their research.
 15. Whenever Significant Financial Interests change or specific events of potential conflict of interest arise, the disclosure is to be updated as soon as possible following the same procedure as for the annual disclosure.

PART II. SUBRECIPIENT/SUBCONTRACTORS CONFLICTS OF INTEREST

DEFINITIONS

Entities with whom OSLC subcontracts a portion of a research project's work are called sub-recipients or subcontractors and are responsible for the same regulations as the prime grantee. It is the prime grantee's responsibility to assure that sub-recipients comply.

Subrecipient Institutions/Investigators and Reporting of identified FCOIs: OSLC is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. OSLC will incorporate as part of a written agreement with a subrecipient terms that establish that the subrecipient will comply with their organization's policy and include time periods to meet disclosure and/or FCOI reporting requirements.

POLICY

Subrecipient Institutions must report identified financial conflicts of interests to OSLC in sufficient time to allow OSLC to report the FCOI to the NIH to meet its reporting obligations.

OSLC will monitor subrecipient's compliance with the FCOI regulation, management plans, and reporting all identified FCOIs to the NIH.

Section 3. Funding and Scientific Research

3/24/2021

PROCEDURES

OSLC will require sub-recipients/subcontractors from other academic or not-for-profit institutions, or governmental entities to comply with this policy and may require:

1. An annual certification from their institutions that they are in compliance with Federal policies regarding Investigator Significant Financial Interest disclosure and that their portion of the project is in compliance with their institutional policies; and
2. A report of any incidents of conflict of interest disclosed by staff under the sub-recipient/subcontractor agreement and actions taken in response to the disclosure.

These requirements will be stated in the subcontract agreement and it will be the responsibility of the Administrative Officer to work with the Principal Investigator to assure that annual disclosures are made.

PART III. AFFILIATED ORGANIZATIONS

DEFINITION

An affiliated organization is an entity that is incorporated independently from OSLC but that shares resources with OSLC under the terms of an Administrative Services Agreement

POLICY

The OSLC SciC has agreed that full disclosure of Research Scientists involvement with affiliated organizations is important in maintaining and building a collegial environment at OSLC and to provide transparency and context for OSLC decision-making. All research scientists will disclose their involvement with organizations affiliated with OSLC.

PROCEDURES

1. Each Research Scientist is required to disclose annually his or her involvement as a board member, advisor, employee or other capacity at affiliated organizations. This will be done by submitting a Disclosure of Commitments form to the COO.
2. The COO will compile the information and send it to all members of the SciC for their information. The information will also be used by administration to assist in tracking level of effort of key personnel as required by grantor agencies.

PART IV. INVESTIGATOR DISCLOSURE OF COMMITMENTS

DEFINITIONS

A conflict of commitment occurs when the commitments to external activities of a Research Scientist adversely affects his or her capacity to meet OSLC responsibilities.

POLICY

3.06 Scientist Conflict of Interest and Conflict of Commitment

OSLC PI Handbook



Section 3. Funding and Scientific Research

3/24/2021

OSLC Research Scientists have agreed that disclosure of commitments beyond OSLC is important in maintaining and building a collegial environment at OSLC. The disclosures are primarily informational. They will be used also in effort reporting and in that context to identify a conflict of commitment. All research scientists will disclose their commitments to other institutions.

PROCEDURES

1. Each Research Scientist is required to disclose annually his or her work for organizations other than OSLC. This includes appointments at other institutions, participation in non-OSLC research, academic commitments, consulting and clinical work, and service of Boards of Directors. This will be done by submitting a Disclosure of Commitments form annually to the COO.
2. The COO will compile the information and send it to members of the SciC for their information. The information will also be used by administration to assist in tracking level of effort of key personnel as required by grantor agencies.
3. Whenever commitments change significantly from the annual disclosure, a new disclosure form should be submitted as soon as possible.
4. Forms to be used with this policy are available on the OSLC Intranet at:
http://intranet.oslc.org/forms/scientist_forms.html
 - Disclosure of Significant Financial Conflicts of Interest
 - OSLC Disclosure of Commitments

PART V. OSLC OUTSIDE EMPLOYMENT POLICY

Approved: 09/12/2009

OUTSIDE EMPLOYMENT

An employee may hold a job with another organization as long as he or she satisfactorily performs his or her job responsibilities with OSLC. All employees will be judged by the same performance standards and will be subject to OSLC scheduling demands, regardless of any existing outside work requirements.

If OSLC determines that an employee's outside work interferes with performance or the ability to meet the requirements of OSLC as they are modified from time to time, the employee may be asked to terminate the outside employment if he or she wishes to remain with OSLC.

If an employee's outside employment has an undesirable impact on OSLC, then OSLC may consider it a conflict of interest interfering with their work.

(See also requirements for Research Scientists below)

KEY PERSONS

Section 3. Funding and Scientific Research

3/24/2021

A key person is any person given that designation in a grant award statement. This includes all PIs and sometimes Co-Is and other staff.

Regulations prohibit any key person from receiving compensation from federal research funds in excess of 1.0 FTE (40 hours per week) across any number of organizations. OSLC activities are primarily funded by federal agencies, either directly (grants, indirect funds) or indirectly (subcontracts). This means, for example, that a key person working for OSLC at .75 FTE is limited to an additional .25 FTE with other employers who are also providing work based on federal funds. Compensation for consultation performed outside of an employment relationship is excluded from this federal limitation.

RESEARCH SCIENTISTS

The role of Research Scientists stretches beyond their particular OSLC project and publishing responsibilities to include participation in the greater scientific community. Participating in grant and journal reviewing, presenting research, consulting and making other scholarly contributions is encouraged as long as these activities do not interfere with the performance of OSLC responsibilities.

Research Scientists may engage in paid activities outside of OSLC, limited to .2 FTE (full time equivalent) total for all commitments for a calendar year. Activities include use of professional capabilities to further the agenda of a third party in return for immediate or prospective gain. Grant reviewing does not count as paid consulting time.

Disclosure of commitments will be made by Research Scientists annually. The purpose is to inform fellow scientists of the type and extent of those activities and to share information about collaborations. Research Scientists are expected to adhere to the limitation of 1.2 FTE total effort.

If a Research Scientist is making an on-going and specific commitment of time outside OSLC, this must be communicated in advance to the SciC and the COO.

OSLC scientists are expected to abide by the 1.2 total effort; however, should a circumstance arise, a Research Scientist may seek approval to exceed 1.20 total effort from the Board of Directors who will inform and consult with the SciC on such cases. Requests will be considered in light of the:

- scientist's ability to perform his/her OSLC responsibilities
- circumstances and duration of the over-commitment
- potential benefit to OSLC from the activity

Normally effort over 1.2 would be considered for a limited time period. In no instance will the time exceed 1.4 FTE.

OSLC PI Handbook

Section 3. Funding and Scientific Research

3/24/2021

