

Conflicts of Interest in Research

Policy No. 10-01-035

Effective Date: March 13, 2013

1. GENERAL

Collaboration between OHSU and others is critical to OHSU's research, healthcare, education, and community service missions including its Technology Transfer program. This policy seeks to foster collaboration by (a) providing guidelines and mechanisms for resolving potential or actual conflicts of interest in research, and (b) safeguarding OHSU and OHSU Investigators' reputation for academic integrity. OHSU intends, by this policy, to comply with applicable federal and state requirements.

2. RULE

For purposes of this policy, a conflict of interest in research exists when an investigator has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research, or may otherwise require management because of the appearance of conflict of interest in research.

3. OBJECTIVES

The Office of Research Development and Administration (RDA) shall seek to:

- A. Safeguard the integrity of OHSU research and educational programs.
- B. Ensure that the academic or professional progress of graduate students, postdoctoral researchers and other OHSU personnel are assigned only research duties consistent with their status or position.
- C. Ensure any significant financial interest of an Investigator which could affect the design, conduct, or reporting of research or educational activities be disclosed and eliminated or managed as appropriate.
- D. Ensure that research sponsors' access to and use of university resources is consistent with OHSU's legal, policy, financial and reputational interests.

4. DEFINITIONS

As used in this policy, the following terms mean:

A. **Designated Official:** The Vice President for Research or individual(s) appointed by the Vice President for Research.

B. **Conflict of Interest in Research (CoIR):** A determination by the designated official that a significant financial interest (SFI) might affect, or reasonably appear to affect, the design, conduct, or reporting of research. Such situations may require management, but may not be found to constitute a FCoI as defined below.

C. **Financial Conflict of Interest (FCoI):** A determination by the designated official that a significant financial interest (SFI) could directly and significantly affect the design, conduct or reporting of the PHS-funded research. A FCoI is a specific type of CoIR.

D. **Institutional Responsibilities:** Investigator's professional responsibilities on behalf of OHSU, which include, but are not limited to, activities such as research, teaching, professional practice, committee memberships, and service on panels such as Institutional Review Boards or Data And Safety Monitoring Boards.

E. **Investigator:** The principal investigator, co-investigator and other OHSU employees or volunteers, or any OHSU research collaborator, including visiting scientists or consultants, responsible for the design, conduct or reporting of research or educational activities or responsible for preparing a proposal for research funding.

F. **Significant Financial Interest (SFI)** includes the following interests of the investigator (and those of the investigator's spouse or registered domestic partner and dependent children), or of any business controlled or directed by the individual or his or her spouse, that reasonably appears to be related to the investigator's institutional responsibilities:

1) Compensation: i.e., anything of monetary value including, but not limited to, salary, gifts, consulting fees, honoraria or other payments for services that is more than five thousand US dollars (\$5,000) in the aggregate over the last twelve (12) months;

2) Equity interests: e.g. stocks, stock options, warrants, contractual rights to acquire or receive ownership interests, or other ownership interests in a publicly-traded company that is more than five thousand US dollars (\$5,000) or any amount in a non-publicly-traded company;

3) With respect to a publicly-traded company, the aggregated value of compensation, as defined above, over the last twelve (12) months and equity interest that is more than five thousand US dollars (\$5,000);

(4) Intellectual property rights: e.g. patents, copyrights and royalty income or the right to receive future royalties under a patent license or copyright;

(5) Non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (e.g. bonus or milestone payments to the investigators in excess of reasonable costs incurred);

(6) Service as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service; and

(7) Reimbursed or sponsored travel (only applies to investigators involved in Public Health Service funded research and their spouse, registered domestic partner or dependent children) that exceeds \$5,000 when aggregated per entity over the last twelve (12) months. Disclosures shall include the purpose of the travel, the identity of the sponsor/organizer, the destination and the duration of the travel, and any other information as requested by the disclosure form or designated official. See exemptions in (6) below.

Significant financial interest does not include:

(1) Interests of any amount in, or income from, investment vehicles, such as mutual funds or retirement accounts so long as the investigator does not directly control the investment decisions made in these vehicles.

(2) Payments to OHSU, or via OHSU to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and OHSU.

(3) Salary and other remuneration from OHSU, including approved faculty practice plan earnings and the distribution of those earnings that may be established by departmental or other similar agreements provided that those agreements and departmental/divisional group plans are approved by the President.

(4) 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

(5) 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.

(6) Reimbursed or sponsored travel that is reimbursed or sponsored by a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an Institution of higher education.

G. *Research*: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. As used in OHSU policies, the term "research" encompasses basic and applied research and product development.

H. *Retrospective Review*: A review conducted of an investigator's activities, SFIs and PHS-funded research to determine whether any such research, or portion thereof, conducted during the period of non-compliance was biased in the design, conduct, or reporting of such research.

5. INVESTIGATOR SERVICE

Service by an investigator on the governing board or as an officer of any sponsor of the investigator's research shall require the prior approval as described in the Outside Activity/Outside Compensation policy (10-01-015).

6. INVESTIGATOR RESPONSIBILITIES

OHSU investigators applying to conduct research:

- A. Are required to familiarize themselves with this policy and identify all SFIs as described herein during all annual or updated Conflict of Interest in Research disclosure submissions;
- B. Are required to complete required training at least every four years, and as otherwise required by OHSU;
- C. Must file, on at least an annual basis, a Conflict of Interest in Research Disclosure in the form approved by Research Development and Administration (RDA). This disclosure is to the investigator's department chair (or other official if delegated by the Unit Leader or department chair). If circumstances change, the investigator must also revise and add new disclosures. This annual disclosure is in addition to the annual disclosure statement covering outside activities required under Policy 10-01-015;
- D. Must fulfill all requests from RDA, designated official, or the Conflict of Interest in Research Committee for more information relative to the investigator's annual or updated Conflict of Interest in Research Disclosure in a timely manner; and
- E. For investigators conducting research funded by PHS only, investigators must:
 - a. Submit an updated Conflict of Interest in Research Disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
 - b. Submit a Conflict of Interest in Research Disclosure as described in 6(A) no later than the time of application for PHS-funded research.

7. FOR RESEARCH FUNDED BY PUBLIC HEALTH SERVICE (PHS) ONLY

A. It is the expectation that investigators will work with the designated official(s) in a timely manner to create a complete and correct disclosure submission of conflict of interest in research disclosures for institutional review. Unless otherwise specified by law or regulation, any review required by the institution shall not have deemed to have started until a complete and correct submission of the Conflict of Interest in Research Disclosure has been provided to a designated official.

B. Reviewing SFIs for Financial Conflict of Interest (FCoI): Only a designated official may determine if a SFI requires additional review to determine if a FCoI exists. Prior to funds being

spent on a new award, or within sixty (60) days of determining a new SFI requiring a review, the designated official reviewing the SFI shall determine whether a FCoI exists and implement a conflict management plan, at least on an interim basis, in accordance with Section 10 below. The FCoI determination is risk based and is made according to internal guidance developed in consultation with the Conflict of Interest in Research Committee.

C. Determination of need for retrospective review: Only a designated official may make a determination that a retrospective review is required. When required, the institution shall complete a retrospective review. A retrospective review must occur in the following circumstances: failure by the investigator to disclose a SFI in accordance with Section 6(E) that is determined by the designated official to constitute a FCoI; failure by the institution to review or manage such a FCoI; or failure by the investigator or institution to comply with a FCoI management plan.

D. Retrospective reviews: Retrospective reviews shall only be completed for PHS research. SBIR or STTR Phase I applications are exempt from retrospective reviews.

E. Determining bias: Only a designated official may determine whether any PHS-funded research, or portion thereof, conducted during a period of non-compliance was biased in the design, conduct, or reporting of such research. If a designated official determines bias was found, a designated official shall promptly notify and submit a mitigation report to the PHS Awarding Component.

8. RESEARCH CONFLICT OF INTEREST COMMITTEE

The Provost, upon recommendation of the Vice President for Research, shall appoint the Conflict of Interest in Research Committee (Committee) composed of not more than ten persons from the faculty. A majority of members of the Committee shall constitute a quorum. In making appointments, the Provost shall seek to maintain a committee diverse among disciplines and departments doing research at the University. Appointments shall be for a term of three years.

Once a committee member completes his or her term, or resigns from the committee, a replacement will be recommended to the Vice President for Research from the departing member's department or discipline. The Committee shall select its chair and establish procedures for its operation.

9. APPROVAL OF CONFLICTS OF INTEREST IN RESEARCH; APPEAL

A. Upon receipt of a proposal to conduct research, the department chair (or other official if delegated by the Unit Leader or department chair) shall review the proposal to acknowledge if all investigators have certified on the Conflict of Interest in Research Disclosure that there is or is not a potential or actual conflict of interest in research, as indicated by an affirmative response on the Conflict of Interest in Research Disclosure form, with any of the requirements or objectives of this policy. Where a potential conflict of interest in research is disclosed, the reviewer may suggest a preferred method of managing the conflict to the investigator and to the designated official and/or the Committee.

B. The Committee or designated official shall review in a timely manner proposals for which a potential conflict has been disclosed to determine whether the interest may reasonably be thought to directly and significantly affect the design, conduct, or reporting of the sponsored research or educational activities.

C. If a CoIR is found, the Committee shall determine how to manage, reduce, or eliminate the conflict and shall inform the investigator and the Unit Leader in charge of the investigator's unit of the decision.

D. An investigator who disagrees with the decision of the Committee may appeal to the Vice President for Research. Such an appeal shall be in writing only and must be made within ten (10) days of the decision of the Committee. An appeal to the Vice President may only be made upon grounds of procedural irregularity that resulted in prejudice to the investigator, new material information that could not have been presented to the Committee or that the decision is in conflict with applicable laws, rules or OHSU policies.

The Vice President shall make a decision within ten (10) days of the date of the investigator's appeal to the Vice President and the Vice President's decision shall be final.

10. CONDITIONS TO MANAGE CONFLICTS

A. The Conflict of Interest in Research Committee may impose conditions to manage a CoIR involving sponsored research including, but not limited to:

- (1) Public disclosure of an investigator's financial interest in any research sponsor or the commercial success of any therapeutic strategy or product that is the subject of any research results being reported;
- (2) Monitoring of any research project by independent reviewers;
- (3) Modification of any research proposal or plan;
- (4) Disqualification of any Investigator from participating in all or a portion of any sponsored research;
- (5) Divestiture by an Investigator of any financial interest in any research sponsor; or
- (6) Severance of any relationship between an Investigator and a research sponsor which may create actual or potential CoIR.

B. The investigator must agree to the conditions imposed by the Conflict of Interest in Research Committee or appeal such conditions as described in Section 9(D) above.

11. MAINTENANCE OF RECORDS; CERTIFICATION AND ENFORCEMENT

A. RDA shall inform those sponsors that require notification of the FCoI and action. RDA shall keep and maintain records of all disclosures and all actions taken to manage any actual or potential CoIR for at least three (3) years beyond the termination or completion of the award or until resolution of any action by any federal agency involving the records, whichever is longer.

B. The Vice President for Research shall certify to applicable federal agencies OHSU's enforcement and management of FCoIs under this policy.

C. The Unit Leader in charge of the Investigator's unit and the Vice President for Research shall investigate and resolve any alleged violations of this policy. They shall take appropriate action to enforce this policy, including, not but limited to, imposing sanctions including termination from employment upon Investigators found to be in violation of this policy. The designated official shall promptly notify the federal sponsor of unresolved FCoI.

12. VICE PRESIDENT FOR RESEARCH

The OHSU Research Integrity Office, under the direction of the Vice President for Research, may provide guidelines, protocols and other procedures where necessary or convenient to implement or administer this policy.

13. IMPLEMENTATION

FCoI determinations, Sections 6(E) and 7 will apply to each grant or cooperative agreement with an issue date of the Notice of Award after August 24, 2012 or when the investigator's next annual conflict of interest in research disclosure submission is due, whichever is earlier.

Background:

- **21 CFR 54.1-6**
- **42 CFR 50.601-607**
- **45 CFR 94.1-6**

Related policies, procedures and forms:

- [Policy No. 10-01-015, Outside Activity/Outside Compensation](#)
- [Policy No. 10-01-020, Conflicts of Interest](#)
- [Conflict of Interest in Research website](#)
- [Conflict of Interest in Research Form](#)

Implementation date:

- **August 27, 2001**

Revision dates:

- **June 5, 2002; December 23, 2002; July 16, 2003; April 16, 2010; November 19, 2010; August 21, 2012; March 13, 2013**

Responsible office:

- **Integrity Office**