This Integrity Department Policy outlines requirements under OHSU’s Policy 10-01-002 Conflict of Interest and Commitment as it applies specifically to conflicts of interest in research.

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1. Policy Statement and Purpose:

OHSU recognizes that the quality of research may be enhanced when members of the OHSU community participate in outside activities and collaborations that complement their roles and responsibilities at OHSU. The purpose of this policy is to:

A. Provide guidelines and mechanisms for resolving or managing any potential or actual Conflicts of Interest in Research;
B. Minimize the possibility that the design, conduct and/or reporting of OHSU Research are affected by actual or perceived biases created by the existence of Significant Financial Interests on the part of the Investigators or the institution;
C. Safeguard OHSU and OHSU Investigators’ reputations for academic integrity;
D. Ensure compliance with state and federal requirements, including those which apply specifically to Conflict of Interest in Research determination, management and reporting for Public Health Service-funded Research.

2. Policy Application: This policy applies to all OHSU Members engaged in Research, regardless of their OHSU FTE status, and non-OHSU Research collaborators abiding by OHSU’s Conflict of Interest policy, henceforth referred to as Investigators.

3. Definitions:

**Approving Authority:** For purposes of receiving and reviewing Conflict of Interest disclosures and Outside Activities, Approving Authorities include:

1) For OHSU faculty: Department Chair or Institute Director;
2) For Department Chairs or Institute Directors: Dean or Senior Vice President;
3) For other OHSU employees: Immediate supervisor.

**Conflicts of Interest:** A Conflict of Interest (CoI) exists when an OHSU Member’s financial interests or other obligations interfere, or appear to interfere, with the Member’s obligations to act in the best interest of OHSU and its missions, and without improper bias.

**Conflict of Interest in Research:** 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.

**Designated Official:** For the purpose of Conflict of Interest in Research disclosures as required under Public Health Service (PHS) regulations, the Senior Vice President for Research or individual(s) appointed by the Senior Vice President for Research.

**Financial Conflict of Interest:** A determination by the designated official that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of research. A Financial Conflict of Interest is a specific type of CoIR.

**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.

**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.

**Significant Financial Interest:** Includes the following interests of the discloser (and those of the discloser’s spouse or registered domestic partner and dependent children):

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 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 (applies to investigators involved in PHS funded research only and not their spouse, registered domestic partner or dependent children). 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.

Exceptions: Significant Financial Interests do not include the following:

(1) Interests of any amount in publicly traded, diversified mutual funds or retirement accounts so long as the OHSU Member does not directly control the investment decisions made in these vehicles.

(2) Payments to the institution, or via the institution 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 the institution.

(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.

4. IMPLEMENTATION

A. Disclosure Requirements: Investigators must use the electronic Conflict of Interest Disclosure system to disclose:

i. All Significant Financial Interests related to their Institutional Responsibilities, whether or not related to their Research;

   1. Additionally, Investigators involved in any Public Health Service-funded Research (42 C.F. R. Part 50, Subpart F and 45 C.F. R. Part 94) must make disclosures no later than at the time of application for such Research and within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) Significant Financial Interests.

   2. OHSU research that may be reasonably considered as related to Significant Financial Interests, before it is initiated.

B. Disclosure Review and Conflict of Interest in Research Management:

   i. The Designated Official or the Conflict of Interest Committee shall review Research proposals in a timely manner when a potential conflict has been identified, with the specific purpose to determine whether the
relevant Significant Financial Interest meets criteria for a Conflict of Interest in Research and, when applicable, a Financial Conflict of Interest.

ii. Unless otherwise specified by law or regulation, any review required by the institution shall not be deemed to have started until a complete and correct submission of the Conflict of Interest disclosure has been received by the Designated Official.

iii. The Designated Official or the Conflict of Interest Committee determines whether to impose conditions to manage any Conflicts of Interest in Research through the issuance of a management plan.
   1. For a summary of Conflict of Interest in Research Committee guidelines for management, see http://www.ohsu.edu/xd/research/about/integrity/coi/upload/CoIR-Management-General-Guidelines.pdf

iv. Any Investigator who receives a management plan under this policy is required to abide by it.

C. Training Requirements:
   i. Training about OHSU’s Conflict of Interest policies and applicable federal regulations must be completed every four years and otherwise as required by OHSU or by regulations for Public Health Service-funded Research.
   ii. Training requirements for OHSU Investigators are found here: https://o2.ohsu.edu/integrity-department/training/index.cfm

D. Involvement of Trainees in Research:
   i. In order to ensure academic progress and development, graduate students, postdoctoral Investigators and other OHSU personnel shall be assigned only those Research duties which are consistent with their positions. Outside Activities or Significant Financial Interests must not influence how duties are assigned.
   ii. Advisors shall report to graduate students’ thesis committees and to the Dean of Graduate Studies any involvement of their significant financial interests or conflicts of interest in the students’ research.

5. Additional Requirements Specific to Research under Public Health Service Conflict of Interest Regulations: For research funded by agencies that abide by the Public Health Service conflict of interest regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, henceforth referred to as the Regulations) the Designated Official or Conflict of Interest Committee is responsible to:
   A. Identify Financial Conflicts of Interests, determine appropriate management, and report them to the funding agency;
      i. Determination of the existence of a Financial Conflict of Interest must occur, along with implementation of appropriate management (at least on an interim basis), prior to the expenditure of funds from a new award or within sixty (60) days of the identification of a new Significant Financial Interest in the course of ongoing Research.
      ii. The timing and contents of Financial Conflicts of Interests report are as outlined in the Regulations.
   B. Retrospective Reviews: In certain instances of noncompliance with the Regulations, the institution is required to conduct a retrospective review of Research for which a Financial Conflict of Interest has been identified.
      i. The purpose of such reviews is to determine whether the identified Financial Conflict of Interest has led to bias in the design, conduct, or reporting of the Public Health Service-funded Research.
      ii. Retrospective reviews are conducted due to:
         1. Failure of the Investigator to disclose a Significant Financial Interest within thirty (30) days of acquiring it or becoming aware of it and which is determined by the Designated Official to constitute a Financial Conflict of Interest;
         2. Failure by the institution to review or manage a Financial Conflict of Interest in a timely manner;
         3. Failure by the Investigator or the institution to comply with a Conflict of Interest management plan that has been implemented for the identified Financial Conflict of Interest.
      iii. Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I funding from the National Institutes of Health is exempt from Retrospective Review.
      iv. Determination of bias:
1. Only a Designated Official may determine, based on noncompliance as noted in Section [immediately above], whether any Research to which this policy section is applicable, or a portion thereof, was biased in the design, conduct or reporting of such Research.

2. If a Designated Official determines the presence of bias in such Research, then the Designated Official must promptly notify the Public Health Service Awarding Component by submitting a mitigation report.

6. Appeals
   
   A. OHSU Members who do not agree to management plans issued under this policy may respond with their concerns to the Designated Official, committee, or Approving Authority who issued the management plan and request further review.
   
   B. The institution’s grievance procedures of policy No. 03-50-001 shall not apply to any decision made by any person or committee in carrying out their responsibilities under this policy.