Policy Title: Financial Conflict of Interest in Research

Responsible University Office:

University Office:	Office for Research, Innovation and Graduate Education
Office Website URL:	http://research.uoregon.edu/
Policy Owner:	Beth Stormshak, Associate Vice President for Research
Email:	bstorm@uoregon.edu
Phone:	6-2152

DATE: July 27, 2012

Policy Concept Form: The policy concept form was approved by the Senior Vice President and Provost on the following date: N/A – Update to current policy.

NOTE: Policy development may not proceed until the policy concept has been approved.

Preamble:
Objectivity of investigators is the foundation for advancing the frontiers of knowledge and the basis for obtaining and maintaining public trust in research. The University of Oregon encourages outreach to and connections with private industry. At the same time, these activities may create potential financial conflicts of interest in research which must be addressed to maintain public confidence in research.

Reason for Policy:

Definitions:
Conflict of Interest in Research ("COIR") means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research, as determined by the university.

Declaration means an Investigator's formal or explicit statement disclosing Significant Financial Interests to the university.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

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 Sponsored Research. Investigator can include but is not limited to: professorial faculty, research associates, emeritus faculty, research collaborators, post-doctoral students, graduate students, visiting scientists, and individuals with courtesy appointments, external collaborators, or outside consultants, regardless of whether paid or unpaid. The term Investigator does not usually apply to, but does not preclude, departmental grant administrators or financial staff. Key personnel named in the project application or sponsor reports or individuals for whom

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credentials (i.e., biosketches) are submitted to the sponsor as a part of the proposal application are considered Investigators.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Management Plan means the prospective plan for COIR mitigation.

Mitigation Report means a retrospective report for COIR mitigation compliant with Sponsor's requirements.

NIH Standards means the U.S. Department of Health and Human Services (DHHS) regulations on Promoting Objectivity in Research (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). It includes any activity for which research funding is awarded through grant, award, fellowship, training, project, or research resources award.

Significant Financial Interest means:

(1) 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. 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 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.

(2) Any reimbursed or sponsored travel (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 the Investigator's institutional responsibilities, including the purpose of the trip, the

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identity of the sponsor/organizer, the destination, and the duration; but not including travel 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 affiliated with an Institution of higher education.

(3) Significant Financial Interest does not include the following types of financial interests:

(i) Salary, royalties, or other remuneration paid by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;

(ii) 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;

(iii) Payment from 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 affiliated with an Institution of higher education for

(a) seminars, lectures, or teaching engagements; or

(b) service on advisory committees or review panels.

Subrecipient means any Investigator outside the university community receiving Research funds from the university through subaward, subcontract, or consortium agreement.

Policy Statement:

At the University of Oregon, the design, conduct, and reporting of Research will be free from real or potential influence by any related Investigator's Significant Financial Interest that constitutes COIR. Each Investigator engaged, or planning to be engaged, in Research is obligated to file a Declaration with the university reciting all Significant Financial Interests that could reasonably appear to be related to his/her institutional responsibilities in accordance with this Policy and university Procedures. The university will determine whether a disclosed Significant Financial Interest constitutes COIR. Each Investigator is obligated to complete a 42 CFR 50.604(b) compliant COIR training program in conformance with university procedures. Within the university, disclosed Significant Financial Interests constituting COIR will be assessed and managed in conformance with NIH Standards and all other applicable federal, state and Sponsor requirements. Outside the university, reports to Sponsors regarding disclosed Significant Financial Interests constituting COIR will be provided in conformance with Sponsor requirements and any applicable federal and State of Oregon requirements. All Subrecipients will certify in writing that their COIR Policy complies with NIH Standards and all other applicable federal, state and Sponsor requirements.

The Sponsor will be promptly notified, in accordance with its requirements, in the event that (1) bias is found in the design, conduct or reporting of Research, including the provision of any Sponsor-required Mitigation Report; (2) an Investigator fails to comply with this policy; or, (3) a Management Plan appears to have biased the design, conduct, or reporting of the Research. The university will complete and document retrospective reviews within 120 days of a determination of noncompliance with the Policy. In the event that a Significant Financial Interest relating to Research to evaluate the safety or effectiveness of a drug, medical device, or treatment is not disclosed or managed in conformance with the Sponsor's requirements and this Policy, the university will require that the Investigator disclose the COIR in each public presentation of the research results and request an addendum to previously published presentations. All COIR-related records will be retained in conformance with 42 CFR 50.604(i) and state

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record retention laws.

Exclusions and Special Situations:

Procedures:

Forms/Instructions/Regulations:

Who is Governed by this Policy:
(Please mark all that apply by double clicking on box)
☒ Faculty
☒ Officers of Administration
☒ Students
☒ Staff
☒ Other: This policy applies to Investigators involved in, or planning to become involved in, Research at the University. This policy supersedes all prior and existing policies on matters related to financial conflicts of interest in research.

Who Should Know this Policy:

This policy applies to Investigators involved in, or planning to become involved in, Research at the University. This policy supersedes all prior and existing policies on matters related to financial conflicts of interest in research.

Cross Reference to Related Policies:

Related Documents:
UO Policy Statement 09.00.05, Potential Conflicts of Interest
http://policies.uoregon.edu/policy/by/1/03000-human-resources/potential-conflicts-interest

UO Purchasing and Contracting Policy
http://pcs.uoregon.edu/pcs_files/Clean_Final_Policy_072910_ag.pdf

Purchasing and Contracting Services, Purchasing Ethics
http://pcs.uoregon.edu/content/ethics

UO Policy Statement 02.01.18, Guidelines for Overload Compensation for Faculty
http://policies.uoregon.edu/policy/by/1/03000-human-resources/guidelines-overload-compensation-faculty

UO Conflict of Commitment Policy (Under development)

Frequently Asked Questions:

Revision/Development History:
Updating: Federal regulations may change the reporting thresholds. RCS is hereby authorized to change the disclosure thresholds to reflect current federal regulations.
Updated: n/a
Revised: October 1, 1995; 2001; April 2009 – Issue date: 06/02/2009
02/08/2010 Policy number assigned

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9/20/2010 Reviewed
7/2/2012 Updated
7/27/12 Policy has been approved as an interim policy. Will be presented to Senate during 2012-13 academic year.

Organizational Category:
(Please mark **only** one by double clicking on box)

- ☐ Administration and Governance
- ☐ Academic and Curricular
- ☐ Human Resources
- ☐ Facilities
- ☐ Students
- ☐ Finance and Business Affairs
- ☐ University Relations
- ☐ Health and Safety
- ☒ Research
- ☐ Information Technology
- ☐ General

POLICY CONSULTATION AND REVIEW

Consultation and review by the following individuals or groups:

Vice President for Research, Innovation and Graduate Education — Date: 7-30-12

Reviewed by Randy Geller — Date: May, 2012
General Counsel

Senior Vice President and Provost — Date: 8/6/12

University of Oregon Senate President — Date:

Click here to add Name or Group — Date:

APPROVED BY:

President or Designee — Signature — 8/11/12 Date

POLICY EFFECTIVE DATE: 8/13/12 KW **(As interim policy)**

ASSIGNED POLICY NUMBER: 09.00.04

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