UNIVERSITY OF OREGON POLICY

FINANCIAL CONFLICT OF INTEREST DISCLOSURE AND MANAGEMENT FOR INVESTIGATORS IN EXTERNALLY SPONSORED PROGRAMS ¹

PREAMBLE
A conflict of interest is a situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity. A primary category of concern is Financial Conflict of Interest (FCOI). This policy addresses such conflicts.

There are multiple regulations and policies at the federal, state, and university level that require the disclosure and management of conflicts involving financial interests of university faculty and staff. They are referenced in Section 9.0, Appendix-1 of this policy.

A separate policy governs Conflict of Commitment (COC) concerns that arise out of time allocations between an employee’s university responsibilities and his/her work involving external entities. Those are covered by a separate policy. See Section 9.0, Appendix-2 of this policy.

1.0 OBJECTIVE
This document sets forth University policy on the disclosure, management, and resolution of significant financial conflicts of interest and pertains only to “Investigators” listed by Principal Investigators on the Electronic Proposal Clearance System (E-PCS) as responsible for the design, conduct, or reporting of sponsored programs at the UO. Sponsored programs include all externally funded research and externally funded programs. Sponsored programs and the E-PCS are managed through the UO Office of Research Services and Administration (ORSA).

This policy is required by and is intended to establish compliance with the U.S. Department of Health and Human Services (DHHS) regulations (42 CFR Part 50, Subpart F) Responsibility of Applicants for Promoting Objectivity in Research and the financial conflict of interest policies of the National Science Foundation (NSF).

2.0 OVERVIEW OF FINANCIAL CONFLICT OF INTEREST
The University of Oregon and its employees are committed to the principle of free, open, and objective inquiry in the conduct of its teaching, research, and service missions. In the fulfillment of these missions, it is natural that opportunities arise for its faculty and staff to develop relationships with external entities and to explore commercial activities. The University encourages such endeavors as they enhance personal competency and benefit the community and the institution.

These interactions, however, create the potential for financial conflicts of interest where an individual’s financial or personal considerations may affect or appear to affect their UO activities related to externally sponsored programs. The existence of a real or apparent financial conflict does not necessarily mean that

¹ Portions of this policy have been adapted from and are used with the permission of Stanford University, Oregon State University and Indiana University at Bloomington.
the activity at issue must be avoided or discontinued. A financial conflict of interest depends on the situation, and not on the character or actions of the individual.

It is through disclosure to the University of Oregon of significant financial interests related to an Investigator’s sponsored program that such activities may be reviewed and, if warranted, managed. The identification of these financial interests does not necessarily imply any improper activities or motives on the part of the individual. This policy establishes that disclosure, review, and management process.

3.0 PERSONS TO WHOM THE POLICY IS APPLICABLE

This policy applies to all “Investigators” in externally sponsored programs at the UO.

“Investigator,” for the purposes of this policy, means the Principal Investigator and any person listed by the Principal Investigator on the Electronic Proposal Clearance System (E-PCS) as responsible for the design, conduct, or reporting of their sponsored program(s). These individuals are listed at the time of proposal submission.

Normally, all senior research personnel should be listed as “Investigators.” All of the following should be considered, to the extent they are responsible for the design, conduct, or reporting of the sponsored program: professorial faculty, research associates, emeritus faculty, research collaborators, visiting scientists, individuals with courtesy appointments. The term “Investigator” does not commonly apply to UO departmental grant administrators or to the financial reporting staff of sponsored programs.

4.0 POLICY

4.1 Required Disclosure to the University of Oregon

Identification of “Investigators”

When Principal Investigators submit funding proposals through ORSA, they must list all “Investigators” (as identified in Section 3.0 of this policy) on their project and ensure that required disclosures to the UO from all listed persons have been submitted. Federal regulations require that disclosures and management plans (if needed) be approved prior to expenditure of sponsored funds, if awarded.

Financial Conflict of Interest (FCOI) Annual Disclosure Form and FCOI Disclosure Attachment

Notifications to the University community of this annual requirement will be coordinated by the Office for Responsible Conduct of Research (ORCR). These forms will require only information that is necessary and will not collect unrelated data. Information to be included on these forms is based on the individual’s financial activities from the prior calendar year (January-December), referred to as the “Disclosure Year.” For example, “Disclosure Year 2008” reflects financial activities between January 2008 and December 2008 even though the forms are completed and submitted in 2009.

By May 1st of each year, all “Investigators” (as identified in Section 3.0 of this policy) are required to complete an FCOI Annual Disclosure Form and submit it to the UO Office for Responsible Conduct of Research. If a “significant financial interest” (see Section 4.2) is indicated on the FCOI Annual Disclosure Form, an FCOI Disclosure Attachment must also be completed and submitted. The May 1st disclosure due date enables individuals to use their annual income tax return information, if needed, to complete the form(s).

Required Submission of Revised Forms

If there is a material change (an acquisition of a significant financial interest) to the information provided on the FCOI Annual Disclosure Form and/or FCOI Disclosure Attachment, a new form must be submitted to the UO Office for Responsible Conduct of Research within 30 days of that change.
4.2 Significant Financial Interests (SFI)

Investigators must disclose “Significant Financial Interests” in an external entity that:

▪ sponsors his/her research or program,
▪ has made or pledged a gift to the University of Oregon that benefits his/her research or sponsored program,
▪ has products, services, or research interests that could reasonably appear to be affected by his/her research or sponsored program,
▪ sells goods or services to the University that will be used in his/her research or sponsored program, or
▪ has another involvement in his/her research or sponsored program (such as a consulting agreement).

“Significant Financial Interest” means:

**(a)** compensation (for the purposes of this policy, this means any monetary or other financial benefit from any external entity [non-UO] and does not include UO salary) that is related to the Investigator’s research or to their sponsored program activities that exceeds $10,000* during the year when aggregated for the Investigator and their family members* or

**(b)** ownership interest exceeding 5%* or equity interest exceeding $10,000* in value in any external entity (non-UO) that is related to the Investigator’s research or to their sponsored program activities when aggregated for the Investigator and their family members.*

(This does not include ‘indirect’ equity interest through mutual funds.)

*The threshold limits and the inclusion of “family members” significant financial interests are requirements of the US Department of Health and Human Services (DHHS) regulations (42 CFR Part 50 Subpart F, 50.503). “Family members,” for the purposes of this policy, is defined as the Investigator’s spouse, domestic partner, and/or dependent children.

4.3 Confidentiality

The FCOI Annual Disclosure Forms, FCOI Disclosure Attachments, and management plans are considered to be confidential personnel information and should be maintained in a secure and confidential file. The information contained in these documents is available only to individuals duly charged with the responsibility for review and management of financial conflicts of interest at the University of Oregon and may be released only in accordance with and as required by federal law, Oregon law or a lawful court order. The FCOI Annual Disclosure Forms and the FCOI Disclosure Attachments may be copied only by the signer and the Office for Responsible Conduct of Research.

Records of and related to FCOI disclosures shall be retained according to University record retention policies and schedules and sponsor requirements.

4.4 Disclosure Review, Management Plans, Dispute Resolution and Appeals

Disclosure Review

The Office for Responsible Conduct of Research (ORCR) will provide timely review of completed FCOI Annual Disclosure Forms and FCOI Disclosure Attachments and will notify individuals upon completion of such review.

Management Plans

Upon reviewing a person’s FCOI Disclosure Attachment, the Assistant Vice President, Responsible Conduct of Research (or designee), after discussion with the person, will decide whether a management plan is needed. Should management of a potential or actual significant financial conflict of interest be required, the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee), and the Assistant Vice President, Responsible Conduct of Research (or designee) will work together to draft a “Management Plan.” These written plans will manage, reduce, or eliminate the significant financial interest(s). Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. Final management plans are reviewed and approved by the appropriate Vice President and/or Vice Provost.
Management plans may include a single element or several elements such as:
   a. monitoring of the sponsored program by independent researchers or reviewers, or the COI Committee or their designee;
   b. modifications to the research or program plan;
   c. appointment of an oversight panel or person to review research/scholarship;
   d. appointment of an oversight panel or person to monitor the use of students and staff;
   e. public disclosure of Significant Financial Interests, including to human research participants, researchers, publishers, and/or conference organizers;
   f. limitations on the employee’s involvement in personnel decisions on behalf of the University;
   g. transfer of purchasing authority;
   h. divestiture of significant financial interests; and/or
   i. other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.

Dispute Resolution
If the Investigator, the head of the responsible unit (or designee), and the Assistant Vice President, Responsible Conduct of Research (or designee) cannot agree on a management plan, the matter will be referred to the UO Conflict of Interest Committee (COIC) (see Section 4.5). In such cases, the Investigator may request that a UO Faculty member of his/her choosing (other than himself/herself) be appointed to the COIC for the review of his/her situation.

The COIC will review the written materials, consult with the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee), the Assistant Vice President, Responsible Conduct of Research (or designee) and/or others as needed. The COIC will make their recommendation to the Vice President for Research and Graduate Studies (VPRGS). The VPRGS, after consideration of the COIC recommendation, shall make the final determination on management plans reviewed by the COIC.

Appeal
If the Investigator does not agree with the recommendation of the COIC, he or she may appeal directly to the Vice President for Research and Graduate Studies. The VPRGS may ask the COIC to provide additional work on the draft management plan. The VPRGS, after consideration of the COIC recommendation and the Investigator’s appeal, shall make the final determination on the management plan.

4.5 Responsibilities of the Conflict of Interest Committee (COIC)
The UO Conflict of Interest Committee is comprised of faculty members and is staffed by the Office for Responsible Conduct of Research (ORCR) personnel.

The COIC has the following primary responsibilities:
   1.) reviewing complex disclosures, as requested by ORCR, to assure that all issues have been considered and addressed;
   2.) reviewing draft management plans where the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee) and the Assistant Vice President, Responsible Conduct of Research (or designee) have been unable to reach agreement and make a recommendation for resolution to the Vice President for Research and Graduate Studies; and
   3.) advising ORCR on implementation and communications regarding the FCOI policy and processes.

4.6 Individual Responsibilities for Compliance
Vice Presidents and Vice Provosts, in conjunction with the appropriate Dean and/or Director, as well as UO General Counsel and the Assistant Vice President, Responsible Conduct of Research (AVPRCR), will ensure compliance with and enforcement of this policy. They also review and approve management plans as needed. The Vice President for Research and Graduate Studies makes the final determination on management plans that he/she reviews as a result COIC recommendations and/or faculty appeals.
Deans, Center/Institute Directors, and Department Heads are responsible for compliance with and implementation of this policy within their schools or departments. The head of the responsible unit (or designee) is responsible for collaborating with the Investigator, the Principal Investigator, as applicable, and the AVPRCR (or designee) in the development, completion, and oversight of management plans within their school, department, center, or institute.

Principal Investigators must list all “Investigators” responsible for the design, conduct, or reporting of their sponsored program(s) on the Electronic Proposal Clearance System (E-PCS) at the time of proposal submission and ensure that each Investigator files an FCOI Annual Disclosure Form as required. If an “Investigator’s” significant financial interest requires a management plan, the Principal Investigator will collaborate with him or her, the head of the responsible unit (or designee) and the AVPRCR (or designee) to develop the plan.

Investigators must submit an FCOI Annual Disclosure Form, and if needed, an FCOI Disclosure Attachment, by May 1 of each year and submit a new form within 30 days if there is a material change (an acquisition of a significant financial interest) to the information provided. Should a management plan be required, Investigators will collaborate with the Principal Investigator, as applicable, the head of the responsible unit (or designee) and the AVPRCR (or designee) to develop the plan. Investigator responsibilities include adherence to management plans.

Subgrantees, Contractors, and Collaborators, who are working under subagreements from the UO that are funded by the Public Health Service (PHS), must comply with the PHS regulations (42 CFR Part 50 Subpart F, grants and 45 CFR Part 94, contracts) by following this UO policy or by providing appropriate assurances to the UO. These individuals must report identified financial conflicts of interest to the Assistant Vice President, Responsible Conduct of Research, 5215 University of Oregon, Eugene, Oregon 97403-5215.

4.7 Monitoring
The Office for Responsible Conduct of Research conducts random and for-cause monitoring of FCOI management plans.

4.8 Remediation and Sanctions
Failure to comply with this policy may prevent individuals from submitting applications for external funding until they have complied.

Failure to comply with this policy may subject a UO employee to sanctions up to and including dismissal, in accordance with Oregon Administrative Rules (OAR), Division 21, Conditions of Service (OAR) 580-021-0320 and OAR 580-021-0325 through 580-021-0385. Such penalties will be adjudicated in accordance with the applicable procedures in the Oregon Administrative Rules and/or the Service Employees International Union (SEIU) Labor Agreements.

Violations of this policy include, but are not limited to:
(a) failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information; or otherwise);
(b) failure to remedy significant financial conflicts of interest; and
(c) failure to comply with a prescribed management plan.

The Office for Responsible Conduct of Research and/or the Office of General Counsel will monitor compliance with this policy.

5.0 ADDITIONAL RESPONSIBILITIES

5.1 Responsibilities of the University of Oregon
The University maintains this written financial conflict of interest policy and will implement a process to identify and manage, reduce, or eliminate conflicting significant financial interests.
The University shall, for any federal research funding from the Public Health Service or any other federal funding agency that imposes these requirements:

a. require subgrantees, contractors, and collaborators working under PHS funded subagreements from the UO to comply with the PHS regulations (42 CFR Part 50 Subpart F, § 50.604 [grants] and 45 CFR Part 94, § 94.4 [contracts]) by following this UO policy or by providing the appropriate assurances of compliance to the UO;

b. maintain the records of and related to FCOI disclosures according to the UO record retention policies and schedules and sponsor requirements. Records shall be maintained by the University for no less than five (5) years after the termination or completion of the research to which they relate;

c. report any conflicting significant financial interest to the awarding component of the funding agency that issued the award prior to the expenditure of funds and that the interest has been managed, reduced, or eliminated;

d. report to the awarding component of the funding agency any significant financial interest identified as conflicting, subsequent to the initial disclosure, and that the interest has been managed, reduced, or eliminated, within 60 days of that identification;

e. make information available, upon request, to the sponsoring agency regarding all identified conflicting interests and how those interests have been managed, reduced, or eliminated;

f. inform the National Science Foundation, Office of the General Counsel, if it is unable to satisfactorily manage a significant financial conflict of interest related to a project funded by the NSF; and

g. provide the opportunity for any UO employee to seek information or request advice on possible financial conflicts of interest without being required to disclose his or her name or identifying details of the potential conflict. Any unit of the University may request advice about a potential financial conflict of interest from ORCR provided that no more identifying information than necessary should be disclosed unless required by law or University policy.

5.2 Responsibilities of UO Offices
Office of the Vice President for Research and Graduate Studies is responsible for the implementation of this policy and provides oversight of the following research units:

Office for Protection of Human Subjects (OPHS) queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed an FCOI Annual Disclosure Form. There is a separate Biomedical Institutional Review Board FCOI policy and process for “Investigators” engaged in funded (including internal and external sources) or unfunded human subject research. This includes invasive human subject research which means the introduction of any substance and/or device into the body or any procedure in or into the body. OPHS will notify ORCR in cases where required disclosure appears not to have occurred.

Office for Responsible Conduct of Research (ORCR) provides assistance and guidance to Faculty and other UO employees, Supervisors, Department Heads, Directors, Deans, Vice Provosts, Vice Presidents, and the Conflict of Interest Committee throughout the FCOI disclosure, review, approval and management processes. The ORCR fulfills the functions described in Section 4.0 of this policy. The ORCR provides training and guidance materials in FCOI regulations, requirements, and obligations.

The Office for Responsible Conduct of Research (ORCR) prepares the annual report to the Oregon University System as well as any other reports required by state, federal or other oversight agencies. The ORCR will do this in conjunction with the appropriate Vice President,
Vice Provost and/or Senior Vice Provost, the Chief Financial Officer, the Provost, President and the Office of General Counsel.

**Internal Management Directive 4.015(9)** requires that the institutional president report to the Chancellor's Office by August 31 of each year any change in institutional policy on outside activities and evidence of procedures followed in monitoring faculty and family acceptance of compensation and equity for outside activities of faculty members. The Office for Responsible Conduct of Research will prepare this report on behalf of the President’s Office.

**Office of Research Services and Administration (ORSA)** collects “Investigator” information as listed by Principal Investigators on the Electronic Proposal Clearance System (E-PCS) and includes FCOI disclosure status inquiries on all new and renewal grant and contract submissions. This information is provided to ORCR, as needed.

**Office of Technology Transfer (OTT)** works collaboratively with innovators and ORCR to ensure that potential conflicts of interest are proactively identified and appropriately managed. OTT is deeply committed to fostering a culture at UO that supports innovation and entrepreneurship through approaches that are open, collegial, non-punitive, consistent, ethical, and timely. UO OTT is a formal signatory to the document "In the Public Interest: Nine Points to Consider in Licensing University Technology," a statement of principles developed at Stanford University to guide university staff as they connect university discoveries to private sector companies and end-users communities. As stated in the Nine Points, the University of Oregon and other research universities strive to address potential conflicts of interest "in a manner that reflects well on [each institution] and its community." Read the Nine Points document at: [http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf](http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf)

**Office of Veterinary Services and Animal Care (OVSAC)** queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed the FCOI Annual Disclosure Form. OVSAC will notify ORCR in cases where required disclosure appears not to have occurred.

**Office of General Counsel**, as designated by the UO Office of the President, advises the UO Conflict of Interest Committee and the UO administration in the FCOI review and management processes. In conjunction with the appropriate Department Head, Director, Dean, Vice President and Vice Provost, as well as the ORCR, the Office of General Counsel facilitates compliance and enforcement of this policy.

### 6.0 GLOSSARY

**Compensation** – for the purposes of this policy, means any monetary or other financial benefit from any external entity (non-UO) and does not include UO salary.

**Equity** – means any ownership interest in any commercial or non-profit entity, including common stock and other equity securities, and any right to acquire any options, warrants or other convertible securities. (This does not include ‘indirect’ equity interest through mutual funds.)

**External Entity** – can be any or all of the following: a natural person (other than yourself) capable of being legally bound, sole proprietorship, corporation, partnership, limited liability company or partnership, limited partnership, for-profit or nonprofit corporation, unincorporated association, business trust, or any other person with legal capacity to contract, a governmental agency or governmental subdivision or any other entity that is external to the UO.

**Research** - means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to society, including the sciences, social sciences, and the humanities. The term encompasses basic and applied research and product development.
Sponsored Programs – include both research and other programs that receive external funding based upon competitive proposals submitted to local, state, and federal agencies and other organizations. Grants and contracts are managed through the Office of Research Services and Administration (ORSA).

7.0 FORMS
- FCOI Annual Disclosure Form (ORCR Form #1.0)
- FCOI Disclosure Attachment (ORCR Form #2.0)

8.0 POLICY APPROVALS

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<th>University Policy # __ Financial Conflict of Interest Disclosure and Management for Investigators in Externally Sponsored Programs</th>
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<td>Approved by UO Senate Resolution Number:</td>
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<td>Paul van Donkelaar</td>
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<td>UO Senate President</td>
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<td>James C. Bean</td>
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<td>Senior Vice President and Provost</td>
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<td>Richard W. Linton</td>
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<td>Vice President for Research &amp; Graduate Studies</td>
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Responsible Executive: Assistant Vice President, Responsible Conduct of Research

Responsible Office: Office for Responsible Conduct of Research

Originally Issued: December 21, 1991

Updating: Federal regulations may change the disclosure thresholds. ORCR is hereby authorized to change the disclosure thresholds to reflect current federal regulations.

Updated: N/A

Revised: October 1, 1995; 2001; April 2009

9.0 APPENDICES
- A-1 Related UO Conflict of Interest Policies and Guidelines
- A-2 Other Related UO Policies
- A-3 References
- A-4 Related Documents
- A-5 Contacts
APPENDIX-1 RELATED UO CONFLICT OF INTEREST POLICIES AND GUIDELINES

University employees should also be aware of and consult other regulations and policies that address financial conflicts of interest and other conflicts of interest.

- UO Policy Statement 09.00.05 (formerly 3.095), Potential Conflicts of Interest
  http://policies.uoregon.edu/policy/by/1/03000-human-resources/potential-conflicts-interest

- Biomedical Institutional Review Board Policy on FCOI for Investigators Engaged in Human Subject Research (Under development)

- UO Purchasing and Contracting Policy
  http://pcs.uoregon.edu/sites/pcs/files/Clean_Final_Policy_072910_ag.pdf

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

APPENDIX-2 OTHER RELATED UO POLICIES

- 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)

APPENDIX-3 REFERENCES

Federal regulations focus on university investigators responsible for sponsored research programs or other externally sponsored grants and contracts. The UO policy described in this document responds to federal regulatory requirements on FCOI. The State of Oregon has FCOI laws that apply to state employees, including those at public universities. The Oregon University System (OUS) 'Code of Ethics' requires individuals responsible for procurement and/or contracting decisions to adhere to these state requirements. State of Oregon rules and OUS Management Directives regulate the outside employment and external activities of state employees.

Federal References
Note: The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the U.S. Federal Government.

U.S. Food and Drug Administration
- 21 CFR Chapter 1, Subchapter A, Part 54, Financial Disclosure by Clinical Investigators

U.S. Department of Education
- 34 CFR Part 74, Subpart C § 74.42, Codes of Conduct
- 34 CFR Part 75, Subpart E § 75.525, Conflict of interest: Participation in a project

U.S. Department of Health and Human Services (Including Public Health Service and National Institutes of Health)
- 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought
- 45 CFR Part 94, Responsible Prospective Contractors

National Science Foundation
• NSF “Investigator Financial Disclosure Policy”
• NSF “Frequently Asked Questions Concerning the DHHS Objectivity in Research Regulations and the NSF Investigator Financial Disclosure Policy”

State References
Oregon Administrative Rules
Division 21 Conditions of Service
• OAR 580-021-0320, Termination and Other Sanctions for Cause
• OAR 580-021-0325 through 580-021-0385

Oregon University System
• Internal Management Directives, IMD 4.111 and 4.015

APPENDIX-4 RELATED DOCUMENTS
• Financial Conflict of Interest Annual Disclosure – Process Flow Chart (Under development)
• Financial Conflict of Interest Annual Disclosure Procedures (Under development)
• Financial Conflict of Interest Glossary (Under development)
• Financial Conflict of Interest Frequently Asked Questions (Under development)
• Conflict of Interest Committee Charter (Under development)

APPENDIX-5 CONTACTS

Please direct any questions you may have regarding this policy to Lynette Schenkel, Assistant Vice President, Responsible Conduct of Research at schenkel@uoregon.edu or 541-346-3472.