

Bylaws

Conflict of Interest Review Committee

Washington State University

Ratified July 11, 2014 – Amended March 22, 2016 – Revised May 17, 2017

The Conflict of Interest Committee (COIC) is a Presidential committee responsible to implement and provide oversight regarding Executive Policy 27 (EP 27) and applicable state and federal law. EP 27 is the Washington State University (WSU) policy addressing conflicts of interest (COI) in research and technology transfer by WSU Research Employees. The following may qualify as Research Employees, as defined in EP 27:

- a) University employees who are responsible for the design, conduct, or reporting of research, including research scientists, postdoctoral research associates, professional staff and graduate students.
- b) Appointees without formal employment status who are obligated to follow the University Faculty Manual and the University policies and procedures. This may include visiting scientists and faculty with appointments in the professorial ranks whose terms of employment and advancement include contributions via scholarly research.
- c) Faculty or administrative staff who directly manage the technology transfer process on behalf of the University including the Vice President for Research (VPR), the Director, Office of Commercialization (OC), and the AVP, Office of Research Support and Operations (ORSO).

The COIC reviews all pertinent COI documentation relating to potential or actual financial COI applications based on federal and state law and University policy. The COIC has the responsibility and authority to (1) assess whether a potential conflict exists, (2) assess the extent of the conflict and (3) manage, reduce or eliminate the conflict before approving the research or technology transfer activity.

1. Membership

- a. The President has discretion to determine the number and composition of the COIC. Currently, the COIC committee is comprised of WSU faculty (Faculty Committee Members) and certain WSU staff and administrators (Ex-Officio Members). The President appoints the COIC Chair and all members of the COIC, but may delegate this duty to the VPR. Faculty Committee Members are typically appointed for a one year term, renewed automatically for up to three years, unless other arrangements are made. Ex-Officio Members are appointed based on holding a specific administrative position.
 - 1) Chair: The Chair of the COIC must be a member of the WSU faculty. The Chair serves a one-year term and may serve multiple terms at the President's discretion.

- 2) Faculty Committee Members are generally appointed from Colleges and campuses that regularly submit COI disclosures/management plans to the COIC.
 - 3) Ex-Officio Members are appointed from various administrative offices that support or have routine interactions with research and technology transfer activities or processes that may be affected by COI.
- b. Member Responsibilities
- 1) Each member is expected to attend and actively participate in meetings.
 - 2) Each member is expected to contribute his or her expertise and perform a reasonable number of assigned tasks.
 - 3) Each member is expected to study the issues or problems which come before the committee in order to contribute to the resolution process.
 - 4) A subcommittee member should participate fully in executing the subcommittee's responsibilities.
 - 5) Each member must keep financial information of individual faculty and investigators confidential to the extent allowed by law and university policy.
 - 6) Each member is expected to follow the standards set out in Executive Policy Manual #4, Electronic Communication Policy, regarding COIC activity.

2. Committee Operation

- a. COIC meetings (Meetings) will be scheduled at least once every three months and as necessary for timely review of potential conflicts of interest and related issues brought to the COIC. Meetings will be held at a reasonably convenient location and sessions will be limited to approximately less than two hours.
- b. Meetings will be conducted according to Robert's Rules of Order except that discussion on an application shall be an open discussion and may only be limited with a vote of 2/3 of the members present and voting on the application.
- c. The Chair of the Committee and the ORSO will develop an agenda for each meeting which shall generally include the following:
 - 1) Minutes from the previous meeting
 - 2) Announcements
 - 3) New applications, annual reports, and renewals
 - 4) Monitoring and Status reports regarding plans previously approved
 - 5) Continued review for plans not yet approved
 - 6) Other business
- d. Quorum: A quorum shall consist of a majority (greater than 50%) of all members which includes both appointed and Ex Officio members.

- e. Minutes: Meeting minutes will be recorded for each meeting. At each Meeting, an ORSO staff person will be assigned to record minutes. Minutes will be distributed to each member at or before the next Meeting.
 - f. Voting: Each appointed and Ex Officio member has one vote. Proxy votes will not be considered. Members who have potential conflicts of interests as a result of relationships with researchers involved in an application should recuse themselves from voting on that application. Voting may be done at a Meeting or through electronic communication methods (which may include e-mail or electronic messaging) for minor review activities or for application reviews initially discussed at a Meeting. A request from any member to discuss an application at a Meeting will cancel the option of voting on it by electronic methods. Approval of a motion during a Meeting, or through electronic methods, must have greater than 50% approval vote and at least a quorum of all members must vote on the motion.
 - g. Subcommittees:
 - 1) Standing Committees are created by a majority vote at a Meeting. The Chair or the ORSO AVP may create an ad hoc committee, but an ad hoc committee cannot make final decisions on a management plan or take other COIC action. Only COIC members may be appointed to any standing committee, but a committee may ask for input and advice from experts as it deems appropriate.
 - 2) The Chair or ORSO AVP may appoint a subcommittee consisting of two or more persons to perform specified tasks within the COIC mandate. At least one COIC member must serve on an ad hoc subcommittee.
 - 3) A subcommittee may adopt such procedures as it deems reasonable and prudent to accomplish its assigned task.
 - 4) Subcommittees shall report to the full COIC by written report and/or by presenting a report at a COIC Meeting.
3. Application Level of Review
- a. Full Committee Review

Applications for COI management plans that are complex and require discussion or require a plan to manage potential conflicts of interest may require a full committee review. Original review of an application must be done during a COIC Meeting. After a proposed management plan has been reviewed at least once at a COIC Meeting, the COIC may vote to approve or not approve the management plan at a Meeting or decide that specific modifications to the management plan are necessary prior to the COIC taking action on the plan. At a Meeting, the COIC may then determine whether the modified plan must be considered at a Meeting or whether it can be addressed through a COIC electronic vote.
 - b. Preliminary Review

The preliminary review is for advising purposes only during the interim period between full COI committee meetings. All applications received by the COI will receive a preliminary review by the Chair (and one or more committee members at the Chair's discretion) prior to the meeting of the full COIC. The purpose of the

preliminary review is to (i) identify and address any egregious conflicts between full committee meetings; (ii) identify applications and inquiries that do not constitute a COI or those that do not fall under the jurisdiction of the COIC; (iii) provide guidance to the applicant prior to the full committee review; and (iv) work with the applicant to ensure that the application and management include sufficient detail and do not lack required elements thus allowing the full committee to perform its review efficiently. Items (i) and (ii) require, at minimum, the consensus of the Chair and one or more of the following, the AG's office, Office of Research Assurances, OC and/or ORSO for any action to be taken without full committee review. The Chair and appropriate subcommittee(s) at the Chairs discretion will perform preliminary reviews relating to items (iii) and (iv).

c. Limited Commercialization Reviews

These are reviews of Conflict of Interest cases that are a result of commercialization efforts initiated by the OC with licensees that do not utilize WSU resources. These Management Plans may be approved by the ORSO AVP utilizing a standard template with the ability to approve minor variations. All necessary compliance and annual reports still apply.

d. Annual Reports

Applications which are determined to require a management plan will require an annual report to be submitted. A reminder will be sent to the Research Employee, and the management plan monitor, a month before the annual report is due. Review of the annual report is intended to assess the effectiveness of the management plan. The annual report may be accepted after an interim review, if the reviewers agree that no change to the management plan is necessary. If the reviewers do not agree, the annual report will be reviewed by the full committee.

Note: Acceptance of an annual report does not indicate the management plan is appropriate if circumstances have changed since the plan was approved. An annual report does not request an amendment of the plan, it is the Research Employee's responsibility to report changes in circumstances that may implicate the management plan.

e. Administrative Review

Some amendments, clerical corrections, and edits may be so minor that full COIC review is not required. The COI Coordinator, ORSO AVP, or COIC Chair may approve such modifications.

f. Inquiries by Investigators

The COI Coordinator may refer an investigator to the Chair or the ORSO AVP, who may provide guidance to help the investigator determine if a COI application submission would be appropriate.

g. Significant Financial Interest (SFI) Sponsor Requirements and Travel Disclosure

The COIC Chair, COI Coordinator, and/or the ORSO AVP or delegate will review SFI and travel disclosures. These administrative reviews will determine if there is any potential for COI which may require the Research Employee to submit a COI application.

4. COI Committee Record Requirements

a. Minutes of meetings

Except as described under subsection 2b, an ORSO representative will take minutes at each meeting of the COI Committee. The minutes will contain information that includes, but is not restricted to, the following items:

- 1) Members present
- 2) Others present (guests/consultants/Research Employees/supervisors of Research Employees)
- 3) Summary of discussion on applications and other issues
- 4) Actions taken during the meeting including motions made and seconded
- 5) Records of voting

b. Retention of records

For all applications reviewed (full review or routine review); application determinations, management plans, decisions, notices and other public records will be retained at the ORSO for the approved retention period.

Meeting minutes will remain on file at the ORSO as a record of the COIC's activities for seven years.

Policy guidance and forms will be disseminated from and stored at the ORSO until replaced by new and/or revised documents.

5. Disclosures to COIC

A Research Employee must promptly disclose all facts and circumstances which may affect the Research Employee's management plan or create a potential COI. Required disclosures include, but are not limited to:

- a. New SFI, as defined in EP 27, if the research involves PHS or other applicable sponsors or creates a potential conflict of interest.
- b. New inventions or Intellectual Property
If the Research Employee must disclose intellectual property or inventions which may in any way relate to the Research Employee's potential conflicts to the COIC as soon as possible, but no later than 30 days after (a) disclosure of the invention or intellectual property to WSU OC, (b) disclosure of the invention or intellectual property to a non-WSU entity related to the Research Employee's potential conflict of interest or (3) if either WSU or the entity creating the Research Employees potential conflict of interest applies for legal protection of the intellectual property; and
- c. New coworkers, students, business associates that may create a potential COI.

6. Modifications/Amendments/Renewals and Updates to Approved COIC Applications and/or Management Plans

a. Minor Modifications/Amendments

Minor amendments to an approved management plan must be submitted to the COIC in writing, which may be via e-mail to the Chair, ORSO AVP, or COI Coordinator. Minor changes are those that relate to conflicts that have previously been disclosed to and acted upon by the COIC.

b. Major Amendments/Modifications

Major amendments are amendments or disclosures that are not addressed or managed under the existing, approved management plan and COIC application. Major amendments require submission of a revised management plan and/or COIC application. Major amendments should be submitted to the COIC within 30 days of the change in facts or circumstances or of knowledge by the Research Employee of a new potential COI.

c. Renewals

Approved management plans may only be applicable for three years, subject to the approval of the annual report. After a three year period, new COI forms are required for COIC review and approval.

7. Non-Compliance

The COIC or any member of the COIC may report an issue of non-compliance or a violation to EP 27 to a supervisor of the Research Employee, the VPR, the Provost, the WSU Internal Auditor, Washington State Auditor, or other person with appropriate authority. Violations of EP 27 may be addressed through the applicable WSU process or policy, including but not limited to the procedures in the faculty manual, Student Code of Conduct or WSU Human Resources Services policies and procedures. If PHS or other applicable sponsor is funding the research, a failure to disclose a SFI will also be addressed as provided in EP 27.