

Conflict of Interest (COI) Student Management Plan Standard Operating Procedure (SOP)
WSU Elson S. Floyd College of Medicine Office of Research

It is the WSU Elson S. Floyd College of Medicine's policy that all faculty and key administrators, with decision-making authority affecting academic programs and students, identify all potential Conflicts of Interest. This is consistent with [College of Medicine Policies](#).

The following Standard Operating Procedure applies to projects where a student's supervisor or sponsor may have COI.

1. When the Institutional Review Board (IRB) or Human Research Protection Program (HRPP) reviewers identify a potential COI, the Office of Research Support (ORSO) and Operations and the College of Medicine Vice/Associate/Assistant Dean of Research (ADR) will be notified.
2. ORSO will initiate the below form and send to the college ADR.
3. The college ADR will review and sign the form confirming that:
 - a. The faculty member is eligible to serve as a PI (Note: this will only be asked for if it is unclear due to rapidly changing faculty and faculty roles within the college), and;
 - b. The COI has been disclosed, the project complies with university policies as addressed in the form and the management plan is appropriate (when required).
4. Prior approval/management plans from ORSO will be required for all projects.
5. The IRB will be emailed confirmation that the COI disclosure has been approved, a copy of the form can be provided to reviewers upon request for expedited and exempt projects and will be provided for all full board reviews (to meet regulatory criteria).



DATE

INVESTIGATOR NAME
UNIT, AREA

Subject: Student Activities between Washington State University and WSU Investigator Company, concerning "Project Title" (Project)

COI Case Number: XXXX-XX

Dear Investigator and Title/Position:

This letter summarizes our review of financial conflict of interest issues related to the above referenced project ("Project") between Washington State University ("University") and WSU Investigator Company ("Company"). This review addresses your disclosure of an ongoing relationship with Company, which has met the definition of Financial Conflict of Interest per [WSU Executive Policy #27](#).

Our primary interest in the management of financial conflicts is with the appropriate and legal use of state resources, facilities, and staff. We also have an overriding concern to protect the ability of all students to freely pursue and publish their research. Hence, our goal is to maintain a clear separation between the activities of the University and Company. Based on our review, we are by copy of this letter updating the XXXXXX ("College") on the status of your conflict management plan related to the above referenced Project, subject to the following conditions:

Disclosures

- a. You are required to make appropriate disclosures of your financial interest(s) in connection with any publication (print, electronic, oral or otherwise) of the results of research at the University related to the Project, as well as to all investigators at the University with whom you are collaborating on related research. For researchers in the biomedical sciences, disclosure in publications should conform to recent uniform disclosure guidelines published by a group of editors of major medical journals (Davidoff et al. JAMA 286: 1232-1234, 2001).
- b. Any student (undergraduate, professional, or graduate) or WSU employee who is involved in any way with this activity shall be advised of her or his rights and responsibilities through the *COI Guidance for Students and Employees* orientation provided by the University Ombudsman office. You may not engage students in Company activities if you have any evaluative authority (e.g., course grading, member of

student's graduate committee) over those students, unless an approved COI management plan is in place for you and your students. See attached **Appendix A** for more information. Notification to the University Ombudsman office of student and/or employee names should occur within 10 days of being involved in your Laboratory or with any Company activities. All WSU employees who are involved in any way with this activity must have a non-conflicted supervisor.

- c. You must disclose to the WSU Office of Commercialization (OC) any Intellectual Property (IP) that is developed by any person who is an employee or student of WSU, using WSU facilities or resources, or working on the Company side of this management plan.

Restrictions

- a. **Human Subjects Research.** You may not participate in a clinical trial involving technology in which you have any IP interest, or involving technology licensed/optioned by the University if you have a substantial equity interest in the License or Option, without prior review and approval by our office.
- b. **Participation in Negotiation and Administration.** Neither you nor any family members, can participate in the negotiation of any University agreements related to research involving the Project or Company, including the licensing of IP rights arising from any such work, unless appropriate waivers are in place.
- c. **Sharing of University Information and IP.** You may not transfer any University research results or IP relating to the Project to Company, except through normal scholarly publication, licensing, or other agreements that are negotiated through the WSU OC or the OR. Any information being provided to Company that was or is developed at the University, including conceptual information not yet reduced to practice, must first be disclosed to the WSU OC prior to disclosure to Company, unless already published and available to any third party.
- d. **Use of University Facilities and Resources.** You and all persons working with you in any University facility must take reasonable measures to ensure that no University facilities or resources are used for the private business activities or other private benefit of Company except as may be specified under terms of official agreements between the University and Company.
- e. **Foreign Nationals.** Foreign nationals with VISA status with the University cannot work in a start-up company as this would be a VISA violation.

Ongoing Compliance

- a. You are reminded of your obligations under the University's [Executive Policy on Ethics, Conflict of Interest, and Technology Transfer \(#27\)](#) and the [WSU Faculty Manual](#), including complying with the conditions of this management plan and the requirement to submit annual reports. In addition:
 - a. If applicable, you are required to obtain prior approval for all outside professional work and remain current in the filing of required outside work approval forms using the ANNUAL REPORT OF CONSULTANT AND EXTENDED PROFESSIONAL ACTIVITIES Form, found at [BPPM 60.44.2](#).

- b. If applicable, you are required to disclose the occurrence of any reimbursed or sponsored travel as outlined in [WSU Executive Policy #27](#).
- b. No University equipment, supplies, materials or animals may be transferred from the University to Company without appropriate contracts with the University.
- c. A Plan Monitor must be designated within 30 days of approval to ensure full objectivity occurred during the course of this relationship. This Plan Monitor shall be identified via email to or.coi@wsu.edu, and would ideally be a superior, or similar level colleague with broad knowledge of the material present in your COI Case, and will need to verify all activities are appropriate via the COI Committee Annual Report Form.
- d. You must not promote, endorse, cite, market, advertise or offer the sale of company products or services (their own company or others) while serving in your capacity as a WSU employee. Use of persons, money or property for private gain is a state ethics violation – this includes any use for commercial purposes such as advertising or selling ([RCW 42.52.160](#) and [RCW 42.52.360\(2\)\(a\)](#)).
- e. If the Company will be involved with a Clinical Trial that has not yet started, you will ensure that a disclosure informing subjects of the COI will be included in the IRB approved Informed Consent Form, which will be reviewed with the rest of the protocol by the IRB. Once the Informed Consent Form has been stamped Approved, you must submit a copy of it to the COI Coordinator to be included with the case file.

Amendments. WSU reserves the right to modify this management plan and to impose new or additional conditions. Such modifications, conditions, and additional terms will be effective immediately and incorporated into this management plan. WSU will notify you of these changes in advance via email. You will be deemed to have accepted these terms and conditions unless you appeal your management plan, which must be done in writing and sent to WSU's Conflict of Interest Committee at or.coi@wsu.edu.

This approval is subject to the understanding of the facts as described above and to compliance with all conditions stated above. If there is a material change in the facts, you are required to report them immediately to the University.

We appreciate your cooperation in assuring compliance with University policies, state statutes and federal regulations governing conflicts of interest.

Sincerely,

Dan Nordquist
Associate Vice President for Research

Cc:
Department Chair/Director
Dean/Chancellor/Delegate

Director, Office of Commercialization
Coordinator, WSU COI Committee

Appendix A – Ongoing Student Compliance Information

- Any graduate student who you accept to mentor for thesis research related to this case will form a graduate thesis committee within one month of starting research related to this case.
- Student graduate thesis committee meetings will be held a minimum of three times throughout the year to discuss experiments, publication strategy, and IP issues.
- Faculty who have no ties to Company will comprise a majority of a student's graduate thesis committee.
- Within one month of starting the student's research related to this case, the Plan Monitor and graduate thesis committee will consult with a student regarding confidentiality agreements with the company and potential impacts on dissertation defenses. Options available for dealing with this situation can be pursued with the Attorney General's Office and may involve a non-disclosure agreement with committee members.
- Within one month of starting their research related to this case, students will meet with the Director of the WSU OC or delegate to obtain information on IP rights.
- Delays in publication or public presentations up to, but not exceeding, 60 days will be allowed for purposes of preparing and submitting relevant patent applications.
- Students who conduct research related to this case while rotating with you as part of their graduate program requirements, but who have not selected you for their thesis advisor, will be treated as described in the foregoing with the exception that there will be no graduate thesis committee involvement.
- Students (as opposed to employed graduate research assistants in the research employee's lab) are not permitted to function as employees of the Company without obtaining prior permission from the chair/director, dean, chancellor (as appropriate), and Provost. The students must be free to pursue publication, advance in their line of study, and publish their thesis or dissertation without restriction per WSU Executive Policy #27.
- If you are an Undergraduate, Professional, or Graduate Student you must complete the *COI Guidance for Students and Employees* and you cannot have a co-owner of the Company as the Chair of your Graduate Committee. If the work on your dissertation will be performed using Company time, resources, or at WSU during Company-allocated time (example: student performing thesis-related work in a Service Center during Company allotted time) you will follow WSU policy for non-academic pursuits, regarding time allocation. You can find this in the Graduate Student Handbook at <http://gradschool.wsu.edu/159-2/>.

