

Conflict of Interest Case Studies

To comply with federal regulations and state laws, all researchers are required to disclose to UCI their outside financial interests related to their research projects. In addition, researchers are also required to disclose their financial interests in publications and presentations related to those research projects to promote transparency, and disclose all inventions arising from those research projects to UCI's Office of Technology Alliances (<http://www.ota.uci.edu/faculty-resources/intellectual-property-at-uci.html>).

The strategies and methods below are examples of safeguards that the Conflict of Interest Oversight Committee (COIOC) may require to address the potential risks of a conflict of interest (<http://www.research.uci.edu/compliance/conflict-of-interest/coi/potential-risks.html>), in addition to UCI's standard publication/presentation and intellectual property disclosure requirements. Please note that each situation is unique and the following safeguards do not guarantee the COIOC's approval.

For researchers with financial interests that are related to their research projects, please consider adding appropriate safeguards as you design your study to proactively address the potential risks of a conflict of interest. **To facilitate the COIOC's review, please highlight the safeguards you have implemented to ensure the objectivity of the research in light of the related financial interests in your Conflict of Interest Addendum.**

Financial Interest Case 1: A Principal Investigator (PI) has equity interests in and received income from Company A, which is sponsoring her research project involving their product.

Safeguards to address potential risks of a conflict of interest:

- The PI established a standard operating procedure that blinds the study, which includes:
 - Non-conflicted Researcher B codes the different compounds to be used in the study.
 - Non-conflicted Researcher C conducts the experiments on the different compounds, including data analysis and graphing. The PI is not involved in the blinding or data collection.
 - The results are presented to the PI, after which the non-conflicted Researcher B reveals the code for the experiment.
- Inventions arising from the related research are reported to UCI's Office of Technology Alliances. The PI will not participate in any decision making process regarding the licensing of the inventions.

Financial Interest Case 2: Professor D is a co-founder of Company E, serves as a scientific advisor and holds equity interests in Company E. Professor D will be PI on subcontract from entity.

Safeguards to address potential risks of a conflict of interest:

- Professor D structures the research team so that non-conflicted individuals will collect data and that he will not be involved in data collection.
- Data will be stored in shared file and discussed in meetings with Professor D, the research team and at least one of Professor D's non-conflicted faculty peers or colleagues, who will be present to provide additional oversight at meetings.
- The Principal investigator on Company E's prime award is not Professor D or anyone else on the UCI research team.
- Scopes of work for Company E and UCI are distinct with minimal overlap.
- Company E will use its own facilities and resources to conduct its portion of the project and will not use any UCI facilities or resources.
- UCI researchers supported by the subcontract from Company E will not engage in consulting activities for the entity for duration of the subcontract.
- Professor D will not represent company or participate in UCI subcontract negotiations.
- Inventions arising from the work performed under the subcontract are reported to UCI's Office of Technology Alliances. Professor D will not participate in any decision making process regarding the licensing of the inventions.

Financial Interest Case 3: Professor F is the founder of NewCo (a new start-up) with no other employees. Professor F conducts research that is directly related to NewCo's interests and future product.

Safeguards to address potential risks of a conflict of interest:

- Adding Professor G – an independent, non-conflicted faculty peer (non-junior to Professor F) – to the related research project to provide a scientific review of the data and reporting. Professor G verifies that data analysis and reporting were done objectively and that the data supports the reported research results.
- Inventions arising from the related research will be reported to UCI's Office of Technology Alliances and assigned to UC Regents, in accordance with UC patent policy and the UC patent acknowledgment. Professor F does not participate in any decision making process regarding the licensing of reported inventions.

Financial Interest Case 4: Professor H received honoraria from Company I, which is sponsoring a clinical trial that is testing the efficacy of Company I's drug and for which Professor H is the PI.

Safeguards to address potential risks of a conflict of interest:

- The research is carried out at multiple sites (nationally and/or internationally) – multicenter study; and/or the study is designed to be double-blinded where the blind is not broken until

after data analysis; and/or the study designed to randomize subject assignment to study arms (e.g., study drug v. standard of care).

- Professor H will not be involved in the data collection, which will be performed by other non-conflicted research team members.

Financial Interest Case 5: Professor J holds financial interest Company K and is conducting related research that involves graduate students. Company K is involved in the research (e.g., sponsoring the research, the research is related to Company K's product, material or intellectual property, etc.) or the research overlaps with Company K's business interest.

Safeguards to address potential risks of a conflict of interest:

*In addition to considering the strategies to protect the objectivity of the research as described in the case studies above, the following steps may be necessary to protect the students

- Professor J discloses to the students of his financial interests and provides contact information for Conflict of Interest staff in the Office of Research should the students have any questions or concerns.
- Adding an Oversight Member to the thesis/dissertation committees of the graduate students to monitor any potential conflict of interest. For more information, please visit: <http://www.research.uci.edu/compliance/conflict-of-interest/coi/grad-students.html>.
- Adding Professor L to the research team as a non-conflicted faculty peer (non-junior to Professor J) who will supervise the students on the project.

Financial Interest Case 6: Professor M holds equity interests in iStartUP, Inc. – a start-up company licensing UC intellectual property. iStartUP will apply for a SBIR award and plans to subcontract a portion of the work to Professor M's lab at UCI. iStartUP's SBIR proposal indicates that Professor M's post-doctoral fellow will serve as the company's PI for the SBIR award.

Safeguards to address potential risks of a conflict of interest:

*In addition to considering the strategies to protect the objectivity of the research as described in the Financial Interest Case 2 above, the following steps may be necessary:

- Once the SBIR project is awarded,
 - The post-doctoral fellow ends his/her affiliation and employment with UCI to solely be the company's employee (COIOC preferred scenario); or
 - The post-doctoral fellow with the support of the Professor M requests in writing to reduce his/her UCI employment appointment to the Vice Provost for Academic Personnel

- The post-doctoral fellow cannot participate on both the iStartUP prime award and the subcontract to UCI.
- There should be a clear distinction between the work the post-doctoral fellow performs as a UCI employee and as an iStartUP employee.
- The post-doctoral fellow and iStartUP employees must not utilize any UCI resources for the company's research and work unless the company utilizes a UCI recharge facility or service and/or leases space in a UCI-owned/operated incubator (such as TechPortal, TechPortal Orange, Beckman Laser Institute Photonic Incubator).
- There should be a clear distinction between all the research and work conducted at the company and the research and work conducted at UCI that can be easily understood by the general public.

Other possible research safeguards and considerations:

- For SBIR/STTR research, review the UCI Guidance at: <http://www.research.uci.edu/policy-library/spa-policies/participation-in-the-sbir-sttr-programs.pdf>.
- Data will be made publicly available after the study has been completed.
- Add an independent, non-conflicted statistician to analyze data.
- Entity will only have access to data and reporting after it is made publicly available.
- Have an independent data safety monitoring board to provide additional oversight.
- In negotiations between the University and a UCI employee's company, a non-UCI representative or employee of the company will represent the company's interests not the conflicted UCI employee.
- Researchers are discouraged from consulting for an entity that is also the sponsor of their research project(s).
- To ensure that separation is apparent, individuals with outside financial interests should not use UCI websites (or otherwise use UCI's names, logos or images) to promote or publicize the entities with which they have a financial interest; and those entities should not use the disclosing individual's affiliation with UCI (or otherwise use UCI's names, logos, or images) for the entities promotional or publicity purposes.
- Hire contract research organization (CRO) to conduct clinical trial including data collection and analysis.
- Non-conflicted, independent faculty peer to conflicted individual conducts procedures and assessments.