Addressing Potential Conflicts of Interest Guidance

Certain federal regulations, state laws, and University of California policies require researchers to disclose to UCI their outside financial interests (see Disclosure Chart) and disclose all inventions arising from those research projects to UCI’s Research Translation Group.

**COI Best Practices Requirements:**

To promote best practices and mitigate potential conflicts of interest, UCI’s standard requirements for financial interests reviewed by the Conflict of Interest Oversight Committee (COIOC) are:

1. Identify a non-conflicted, independent individual of equal or higher rank to the Disclosing Individual (researcher with financial interest that requires COIOC review) who can serve as the “COI Point Person,” a person the research project team can contact about any COI related questions or concerns. For more information on the COI Point Person role, visit [here](#).
2. Disclose your related financial interest(s) to the study team involved in the project, by emailing them about your related financial interests and who the COI Point Person will be (with the COI Point Person copied). For an example email, visit our website [here](#). Please submit a copy of that email along with the Addendum for documentation purposes.
3. Disclose your COIOC reviewed financial interest(s) in the publications, presentations, and human subject informed consent (if applicable) for the related research project. For examples, visit [here](#).

For researchers with financial interests related to their research projects, please review the following examples and consider adding appropriate safeguards as you design your study to proactively address the potential risks of a conflict of interest and protect the objectivity of the research. To facilitate the COIOC’s review, please highlight these safeguards in your Conflict of Interest Addendum. Please note that the following safeguards do not guarantee the COIOC’s approval because each situation is unique.

**Research Safeguards and Considerations**

As the Disclosing Individual (researcher with financial interest that requires COIOC review), please highlight the safeguards you included in your study on your Conflict of Interest Addendum form and consider adding one or more of the below to help address the remaining conflict of interest risks.

<table>
<thead>
<tr>
<th>Category</th>
<th>Safeguards and Considerations</th>
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</table>
| **Study Design**    | - Non-conflicted, independent faculty peer to the Disclosing Individual that conducts procedures and assessments  
                      - Randomizing subjects  
                      - Masking researchers. For example, a non-conflicted researcher codes different compounds to be used in a study while another non-conflicted researcher conducts the experiments, including data analysis and graphing. The Disclosing Individual is not involved in the masking or data collection and only sees the results after the first non-conflicted researcher reveals the code for the experiment |
• Disclosing Individual participates in data collection because they include a blind to prevent them from knowing which patients are enrolled in each study group (for clinical trials)
• Multi-center study
• Highlight all study aspects in which the Disclosing Individual will not participate, including but not limited to: consenting participants; determining enrollment criteria; data collection; data analysis; and/or reporting

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<thead>
<tr>
<th>Research Data &amp; Analysis</th>
<th>Store and share data in a way that tracks who accesses them and whether they made changes</th>
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<tr>
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<td>An independent, non-conflicted statistician analyzes the data</td>
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<td></td>
<td>Disclosing Individual will not have access to the raw data; data will be blinded by non-conflicted researchers who will only reveal the code after they present the results to the disclosing individual</td>
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<td>Data made publicly available after completing the study</td>
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<td>Entity that Disclosing Individual has financial interests in will only have access to data and reporting after it is made publicly available</td>
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<td>Have an independent data safety monitoring board to provide additional oversight</td>
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<td>A contract research organization (CRO) conducts data collection and analysis for the clinical trial</td>
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<tr>
<th>SBIR/STTR</th>
<th>Review the Guidelines for UCI Employee Participation in the SBIR &amp; STTR Grant Programs</th>
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<tr>
<td>Special considerations for SBIR/STTR research.</td>
<td>For National Science Foundation (NSF) SBIR/STTR Phase I studies, NSF does not allow an equity holder, employee, or officer of the proposing small business to be paid under a subaward without an exception that is recommended by the NSF Program Director and approved by the NSF Division Director for the Division of Industrial Innovation and Partnerships.</td>
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<tr>
<th>Students and Postdocs</th>
<th>Arrange to have a non-conflicted peer researcher supervise/advise or co-supervise/advise the students and postdocs on the study (see COI Liaison)</th>
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<tr>
<td>Steps taken to protect student academic progress and the postdocs’ careers</td>
<td>UCI Related Policies:</td>
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<td>UC Conflict of Commitment policies require that faculty members obtain prior approval through UC OATS before involving a student in an outside professional activity. For more information, please contact your Academic Personnel representative.</td>
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<td></td>
<td>When a faculty advisor has a financial interest related to the student’s dissertation or work, Graduate Division policy requires adding a COI Oversight Member if a student has advanced to candidacy and if the dissertation committee selection process has started. For more information, contact Andrea Bannigan (<a href="mailto:alanders@uci.edu">alanders@uci.edu</a>).</td>
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<tr>
<th>Research Personnel</th>
<th>Arrange to have a non-conflicted peer researcher supervise/advise or co-supervise/advise the research personnel</th>
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| Steps taken to protect the research personnel | on the study, which could include reporting any research objectivity concerns to the department chair/research unit leader and COI staff in the Office of Research (see COI Liaison)  
- Disclosing Individual informs their Department Chair/Research Unit Director of their financial interests, and regularly meets with them to discuss research progress and any research project-related changes, including changes to their financial interest |
| Business Transactions with UCI and Outside Entity | Steps to help adhere to the Disqualification Rule from the California Political Reform Act  
- In negotiations for research awards, service agreements, procurements, and licensing between the University and a company, UCI will only negotiate with a company employee (on behalf of the company) who does not have any active UCI affiliations.  
- Disclose your financial interest to your Department Chair/Research Unit Director to enlist their help in avoiding conflicts of interests in business transactions |
| Outside Consulting  
Highly recommended best practices | Request that Beall Applied Innovation review your personal outside consulting agreement with an entity to confirm that intellectual property provisions are consistent with UC policies  
- Note: All inventions created by UCI employees during their UCI period of employment need to be disclosed to the Research Translation Group at Beall Applied Innovation, including any inventions generated by UCI employees under a consulting agreement with an outside entity. Ownership of inventions created under a consulting agreement are reviewed by RTG and if such invention does not fall under the scope of employment, then UCI will provide a letter confirming that the University will not assert rights in such invention. Contact the RTG team at cove@uci.edu.  
- The scope of work in a researcher’s personal consulting agreement with an entity should not overlap with the scope of work of any UCI research projects or proposals. In addition, the consulting agreement should not augment the scope of a UCI research project which reasonably should be done as a single effort through the UCI research project. If an invention does overlap with any past or present UCI research projects, then such inventions would be considered to fall under the scope of employment  
- The services provided by the researcher can be provided without the using UC funds, facilities, time, or resources. |
| UCI Leadership/Management Position  
Steps taken to address general COI concerns (in addition to COI in research concerns) from individuals | Conflicted researchers who are, or will be, in a UCI research unit leadership/management position (e.g., ORU or center director) related to their company should engage with their home department, School, and/or the Vice Chancellor for Research to develop a conflict of interest plan that addresses the academic and business conflict of interest risks. |
| with UCI leadership/management positions and related financial interests | o This plan may include: identifying the transaction types from which the conflicted researcher should recuse themselves, and home department review of the project management activities (e.g., rebudgeting requests related to UCI subcontracts to the company, invoices claiming costs incurred by the company, applications and proposals for new sponsored awards, IRB and IACUC protocol applications, etc.) related to their company

- The conflicted individual must recuse themselves from decision making involving the purchase of items or services from the entity in which the conflicted individual has a financial interest; decision making should be made by a non-conflicted individual who is administratively senior to the conflicted individual
- Disclose the related financial interest to the Center/research unit team members to promote transparency and identify a non-conflicted individual of suitable academic or administrative rank for them to contact if there are any concerns |

| UCI Name, Logo, Images Avoid any perception that UCI is promoting or endorsing any outside entity | • Individuals with outside financial interests should not use UCI websites (or otherwise use UCI’s names, logos, images) to promote or publicize the entities in which they have a financial interest. In addition, those entities should not use UCI’s names, logos, or images for the entity’s promotional or publicity purposes |
Case Studies

The below cases studies highlight some but not all mitigating factors that may reduce real or perceived conflict of interest, in addition to UCI’s required COI best practices. Please note that the following safeguards do not guarantee the COIOC’s approval because each situation is unique.

General

Financial Interest Case 1: Professor A is the founder of NewCo (a new start-up) with no other employees. Professor A conducts research that is directly related to NewCo’s interests and future product.

Research Safeguards:

- Add Professor B, an independent, non-conflicted faculty peer of at least equal rank to Professor A (see COI Liaison) to the research project, and Professor A discloses their financial interest in the company to Professor B and the research project team.
- Professor B provides scientific review of the data and verifies that data analysis and reporting are done objectively and that the data supports the reported research results. Professor B co-supervises the research personnel. See COI Liaison for documentation requirements.
- Professor B brings any research objectivity concerns to the department chair’s/research unit leader’s attention and/or COI staff in the Office of Research.

SBIR/STTR subcontracts or entity sponsoring research

Financial Interest Case 2: Professor A is a co-founder of Company X, serves as a scientific advisor and holds equity interests in Company X. Professor A will be PI on a subcontract from entity validating the Company X’s sole product.

Research Safeguards:

- Professor A structures the research team so that other non-conflicted research team members perform data collection.
- The team uses shared files to store data, which they discuss with Professor A in a group setting with at least one of Professor A’s non-conflicted faculty peers or colleagues present to provide additional oversight and to help ensure objectivity.
- The principal investigator on Company X’s prime award is not Professor A or anyone else affiliated with UCI.
- Scopes of work for Company X and UCI do not overlap.
- Company X 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 X will not engage in consulting activities for the entity during the subcontract performance period.
- Professor A will not represent the company in subcontract negotiations with UCI.
• Professor A may not negotiate the subcontract on UCI’s behalf but may provide information to UCI negotiators and respond to their questions.
• UCI negotiators consult with and secure concurrence from Professor A’s department chair/unit leader regarding subcontract negotiations requiring policy or procedural exceptions.
• Professor A regularly meets with their department chair/unit leader to keep them informed about research progress, and any research project-related changes, including changes requested by the company and changes in Professor A’s financial interests in the company.
• Research team members discuss research objectivity concerns with the department chair/research unit leader and/or COI staff in the Office of Research.

Human Subjects Research

Financial Interest Case 3: Professor A received honoraria from Company I, which is sponsoring a clinical trial that is testing the efficacy of Company X’s drug and for which Professor A is the PI.

Research Safeguards:

• The research is carried out at multiple sites (nationally and/or internationally) where Professor A is not PI for any site other than UCI.
• The study is designed to be double-masked where the mask is not broken until after data analysis.
• The study is designed to randomize subject assignment to study arms (e.g., study drug v. standard of care).
• Professor A will not be involved in the data collection, which will be performed by other non-conflicted research team members.

Financial Interest Case 4: PhD student A has an ownership interest in a startup company, Company X. For their dissertation, they plan to conduct a qualitative study involving human research subjects. The study is unfunded and involves an anonymous survey tool that is the company’s product.

Research Safeguards:

• Company X’s product was previously validated, and currently being sold and used widely.
• The study seeks to develop a better understanding of product utilization patterns, not product validation or testing.
• The PhD student’s faculty sponsor/advisor has no financial interest in Company X.
• The faculty sponsor/advisor is aware of the related financial interest, will provide COI oversight for the study as a non-conflicted researcher, and will supervise any other students involved in the study. See COI Liaison.
• The conflicted PhD student will not be involved in the data collection.
• UCI’s name, brand, and logo will not be used in the survey materials in this study to avoid the appearance that UCI resources were used for marketing research for a private entity.
The results from this study will not be used to benefit or promote the Company X or the Company X’s product.

Financial Interest Case 5: Professor A has a company, Company X, and would like to conduct a human subjects research project at UCI to validate the Company X’s product.

Research Safeguards:

- Company X funds this study through a research contract that covers all project costs, as required by UCI policy, to avoid the appearance that UCI is utilizing its resources to benefit a private entity. Professor A is not involved in contract negotiations and does not sign the contract on behalf of the company.
- Professor A removes themself from the first pass of the data analysis, and the analyzed results will be shared simultaneously with them and a non-conflicted peer faculty member via a shared Google Drive. A non-conflicted laboratory researcher retains a copy of all research results on their personal UCI Google Drive to which Professor A does not have access.
- Professor A’s department chair is involved in this study and has no financial interest in the Company X. The department chair is aware of the related financial interest and will provide COI oversight for the study as a non-conflicted researcher and attend laboratory meetings. See COI Liaison for documentation requirements.
- Once a quarter, each laboratory researcher will prepare a summary of the data collected for presentation to all lab members and review by the department chair as the COI Liaison. For graduate students and postdocs, this data will be presented twice a year in campus forums where multiple faculty and trainees will be present and review the data.
- Data analysis (sequencing) will be conducted and analyzed in collaboration with a non-conflicted bioinformatician.

Graduate Student Involvement

Financial Interest Case 6: Professor A has a financial interest in Company X and is conducting related research that involves graduate students (no other faculty members involved in the project). Company X is involved in the research (e.g., sponsoring the research, the research is related to Company X’s product, material, or intellectual property, etc.) and the research overlaps with Company X’s business interest.

Research Safeguards:

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 graduate students.

- Add a COI Oversight Member to graduate student thesis/dissertation committees to monitor any potential conflict of interest. For more information on this Graduate Division policy and procedure, please visit here.
• Add Professor B to the research team as a non-conflicted faculty peer (non-junior to Professor A) who will supervise the students on the project (COI Liaison).
• The students will have quarterly lab presentations and create reports that will be reviewed by the non-conflicted faculty peer, Professor B. See COI Liaison for documentation requirements.
• Professor A removes themselves from the first pass of data analysis and will only have access to the primary data after the first pass. The analyzed data will be simultaneously and separately shared with them and Professor B, the non-conflicted faculty peer. The data will be kept on a Drive that is Professor A cannot access.
• Professor A will inform their department chair/research unit leader of their financial interest.
• Professor A’s department chair will attend the lab meetings and be identified as another person that the study team can report any concerns to. See COI Liaison for documentation requirements.
• The study team discuss their research objectivity concerns with Professor B, and/or the department chair/research unit leader, and/or the COI staff in the Office of Research.

Financial Interest Case 7: Professor A 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 A’s lab at UCI. iStartUp’s SBIR proposal indicates that Professor A’s post-doctoral fellow will serve as the company’s PI for the SBIR award.

Research Safeguards:

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

• Once the SBIR project is awarded,
  o The post-doctoral fellow ends their affiliation and employment (including WOS appointments) with UCI (COIOC preferred scenario); or
  o The post-doctoral fellow with the support of the Professor A submits a written request to reduce their 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, Beckman Laser Institute Photonic Incubator, etc.).
• 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.