Conflict of Interest Update

Nadia Wong
COI Administrator
Research Engagement & Facilitation
Office of Research
Research Engagement & Facilitation

• Goal: Encourage research compliance through problem-solving and outreach

• Team:
  – Marci Copeland (Export Control Officer)
  – Nadia Wong (COI Administrator)
  – Amy Green (COI Analyst)
<table>
<thead>
<tr>
<th>Who Discloses</th>
<th>State of California (Non-governmental Sponsors)</th>
<th>National Science Foundation (NSF)</th>
<th>Public Health Service (PHS)</th>
<th>Human Subjects Research</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Principal Investigator (PI) &amp; Co-PI</td>
<td>All Investigator(s)</td>
<td>All Investigator(s)</td>
<td>Research Personnel listed on protocol</td>
</tr>
</tbody>
</table>
| What to Disclose | Financial interests in sponsor:  
  • Income >$500  
  • Investments >$2000  
  • Management position  
  • Loan >$500  
  • Personal Gift >$50  
  • Travel Reimbursements | Financial interests related to project  
  • Income > $10,000  
  • Equity Interest > $10,000 or 5%  
  • Intellectual Property (excluding those owned by UC Regents) | Financial interests related to institutional responsibilities  
  • Publicly traded entity (total compensation & equity interest > $5000)  
  • Non-publicly traded entity (compensation > $5000 or any equity interest)  
  • Intellectual Property income >$5000  
  • Any reimbursed or sponsored travel | Financial interests related to project  
  • Income > $10,000  
  • Publicly traded company (Equity Interest > $10,000 or 5%)  
  • Any equity in privately held company  
  • Intellectual Property (excluding those owned by UC Regents) |

COI Review Considerations

- **Tabled**: Further review and/or changes required
- **Approved**: Objectivity of research
  - UC Policies
  - Obligations to University
  - Public perception
  - Students’ academic progress
## COIOC Review Levels

<table>
<thead>
<tr>
<th>Administrative</th>
<th>Expedited/Subcommittee</th>
<th>Full</th>
</tr>
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<tbody>
<tr>
<td>• Conducted by the COI Administrator on a rolling basis</td>
<td>• Conducted by COIOC Members through email on a rolling basis</td>
<td>• Conducted at the in-person monthly COIOC meeting (3rd Thursday of each month)</td>
</tr>
<tr>
<td>• For financial interests the COIOC has identified as low risk for conflicts of interest</td>
<td>• Primarily for financial interests that have a moderate risk but have been reviewed before</td>
<td>• Primarily for new higher risk financial interests</td>
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<td>• To facilitate the full committee review, COI Staff conducts pre-reviews for these types of disclosures</td>
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</table>
Tips

• New financial interest (especially if related to research)- Recommend that individual contact COI Administrator to proactively address potential COI concerns and avoid delays in the COI review process (earlier the better)

• Form 700U (Non-governmental Sponsor)
  – Require scanned copy of completed form with handwritten signature for COI review
  – Researchers are responsible for submitting their original, wet-ink signed 700U to the Office of Research

• IRB Disclosures
  – Lead Researcher and Administrative staff completing IRB application should check with all research personnel whether or not they have any disclosable financial interests related to the protocol to avoid errors and delays
Tips

- KC 700U Question: Has this proposal been awarded or is it for industry sponsored research including clinical trials?
  - No- standard proposals that you do not know if will be awarded- Officer requests 700U at award stage
  - Yes- other proposals that will be awarded- Initiator required to upload the 700U in KC Proposal
Tips

• COI Team requests for additional forms and copies administrative contact in our records through email
  – Encourage faculty members to respond in a timely manner to avoid delays in their reviews
  – If you are not the correct administrative contact, please forward the email to the correct person

• Multiple COI policies may apply to the same research project depending on who the sponsor (and if applicable prime sponsor) are, and whether the study involves human subjects research
COI Improvements In Progress

- **KC COI**
  - Developing a fully electronic COI system with ERA Team and Kuali Co.

- **Industry Supported Clinical Research**
  - Developing a streamlined process to combine the COI review for these projects with Clinical Trial Administration, Industry Sponsored Research, SPA, ERA, and IRB
  - Proposed New Procedure: Require an uploaded 700U in the IRB application so COI has all the information necessary for the review
  - Potential Effects:
    - Recommend shortening or eliminating the time between submissions of proposal and IRB applications for a project
    - Improved communication between Officers and IRB
    - Less confusion from faculty since there would be one COI review for their project
Questions? Any feedback or suggestions?

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