When, Where, How to Report Information about Financial Interests in Research at UC Davis

March 9, 2018
Cindy Gates, JD CIP CCRP
Director, IRB Administration
Please note: This presentation is to guide researchers in reporting related and significant financial interests when conducting human subject research. It does not cover any other requirements for reporting income received.
I get really confused when I receive Income from entities outside of UC Davis. I don’t know what to report.

It is so confusing!
I don’t know whether I am supposed to report to the Conflict of Interest Committee or the IRB or both!
The problem is that regulators and the State of California have different requirements for reporting.
IRB Requirements for RFIs

COIC Requirements for SFIs
IRB Requirements for RFI
Policy

Investigators and research staff must report Related Financial Interests to the IRB.

Ok… What’s a related financial interest?
Related Financial Interest

Who: Researcher, researcher’s spouse, domestic partner, children, and dependents.

What: Any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor

- Involvement in the design, conduct, or reporting of the research;
- Ownership interest
- Compensation in the past year excluding compensation for costs directly related to the research;
- Proprietary (patent, trademark, copyright or licensing agreement);
- Board or executive relationship;
- Compensation for travel by an entity other than a federal, state, or local government agency, education institution or affiliated research institute, academic teaching hospital, or medical center.
When to report to the IRB
1. In the Initial Review Application
2. Within 30 days of knowledge of newly acquired RFI during the course of the research as an amendment.

What to report to the IRB
1. Nature of conflict (e.g. income, board membership, etc)
2. Amount of income or estimate of anticipated income
3. Reason for income (consulting, presentations, etc.)

Note: You can submit copies of the COIC Forms 700-U, 800 and/or Supplemental Form, if you prefer.

I really like that I can estimate income and reduce the number of reports I have to file!
I like it too! I can estimate and report the amount of income I believe I will receive over a period of time. I won’t have to file so many reports!
But I have to remember – if my income exceeds the estimate, I have to report that additional income within 30 days of receipt.
That’s it for reporting RFIs to the IRB – but investigators also have to report to the COIC – and the reporting requirements are different!
COIC Requirements for RFIs
Reporting to COIC takes a little more thought. Requirements are based on funding.
Significant Financial Interest (SFI)
Anything of significant monetary value, including but not limited to:
- Salary or other payments for services; equity interests (e.g., stocks, stock options or other ownership interests);
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an officer, director, agent, or employee of a business entity.

SFI includes such interests held by a Principal Investigator or other Investigators and by their spouses, domestic partners and/or dependent children.

This definition is very similar to the RFI definition…..I wonder if the report requirements are also similar
Privately Funded Research
1. **Why**: California requirements
2. **Who**: All investigators on human research study.
3. **How**: Online Form 700-U. If “yes” to any questions on 700-U, Supplemental Form must be completed.
4. **When**: Before study start-up and when new research funds are received.

Research Funded by PHS
(And any other Entity that has Adopted PHS Rules)
1. **Why**: regulations & guidance require reporting
2. **Who**: Principle Investigator & all other Investigators
3. **How**: Form 800 (online)
4. **When**: Before study start-up, annually and for every new SFR.

Federally Funded other than PHS
(Entity that have not adopted PHS Rules)
1. **Why**: regulations & guidance require reporting
2. **Who**: Principle Investigator & all other Investigators
3. **How**: Form 800 (online)
4. **When**: Before study start-up and when new research funding is received.

COIC
Human Subject Research
What to Report and When to Report It
### Human Subject Research
What to Report and When to Report It

<table>
<thead>
<tr>
<th>Event</th>
<th>IRB</th>
<th>COIC PRIVATE FUNDING</th>
<th>COIC PHS FUNDING</th>
<th>COIC OTHER FEDERAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before study start-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New research funding is received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 30 days of receipt of new RFI income</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 30 days after new SFI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
I think I understand now.