Related Financial Interests

Revised Reporting Requirements for the IRB (12.4.2018)
Investigators must report RFI w/i 30 days of knowledge that the funds were received.

There is no minimum threshold for the first report of an RFI.

If the RFI is < $35,000, the report will be reviewed at the expedited level.
Investigators must report 12 months previous income and predict 12 months of future income.
<table>
<thead>
<tr>
<th>Committee Review - Greater than Minimal Risk Studies</th>
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<tbody>
<tr>
<td>✓ RFIs received with initial review</td>
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<tr>
<td>✓ RFIs received at continuing review</td>
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<tr>
<td>✓ RFIs that exceed $35,000 during a review interval</td>
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<td>(between initial review and continuing review)</td>
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<td>✓ RFIs that exceed the assigned reporting threshold*</td>
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<tr>
<td>✓ RFIs that involve stock ownership in a private sponsor with a value that is unknown</td>
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<td>✓ RFIs showing an employment relationship with the sponsor</td>
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Determinations:

- Management Plan

- Reporting Threshold - How much more money can accumulate from the same entity without requiring additional disclosure?

Example: Initial report $25,000
Determination: Disclosure
Next report due if income from the same entity exceeds $30,000.
### Full Committee Review

#### Examples

- PI is on the Board of Directors of Sponsor
  - Management plan
  - Trigger for next report

- PI owns 30% of the equity in the sponsor, a private corporation
  - Management plan
  - Trigger for next report

- PI received $65,000 for teaching other PIs how to implant and manage an investigational electronic device
  - Management plan
  - Trigger for next report

- PI developed the investigational device under study
  - Management plan
  - Trigger for next report
The IRB reviewed the information you submitted about a related financial interest (RFI) (person with RFI) has with (sponsor) and determined information about the RFI must be disclosed in the informed consent document using UC Davis standard disclosure language.

If (person with RFI) receives more than (threshold) from (sponsor) before (date continuing review report form is due), you must report this income as a modification within 30 days of receipt of the income.

If (person with RFI) does not receive more than (threshold) from (sponsor) before (date continuing review report form is due), you must report any additional income received on the Continuing Review Report form.
If RFI is <$35,000 ➔ Expedited Review

Expedited Determinations:

• Management Plan – Should almost always be disclosure

• How much more money can accumulate from the same entity without additional disclosure?

Example: Initial report $3500.
Determination: Disclosure
Next report due if income from the same entity exceeds $30,000.
Examples for greater than minimal risk clinical trials:

1. 3 months after initial review, PI reports $5,000 income and $10,000 income between the date of the report and the date the Containing review report is due.

2. During initial review, Committee reviewed the initial disclosure of $3000 income received and $3000 projected and set a limit of $25,000 between the date of review and the date the Continuing Review Report is due. 6 months later PI reports additional income of $26,000.

3. Designated reviewer conducted review of initial disclosure of $12,000. Set limit of $18,000. Prior to continuing review PI submits report of $20,000 income.

I keep forgetting to include the projected income.
Questions?