



Related Financial Interests

Revised Reporting Requirements for the IRB (12.4.2018)

Reporting Requirements



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.

Reporting Requirements at Initial Review



Investigators must report 12 months previous income and predict 12 months of future income



Committee Review - Greater than Minimal Risk Studies

- ✓ RFIs received with initial review
- ✓ RFIs received at continuing review
- ✓ RFIs that exceed \$35,000 during a review interval (between initial review and continuing review)
- ✓ RFIs that exceed the assigned reporting threshold*
- ✓ RFI's that involve stock ownership in a private sponsor with a value that is unknown
- ✓ RFIs showing an employment relationship with the sponsor

Full Committee Review

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





Approval Letters

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.

Expedited Review

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 Continuing 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?