

The IRB – COI Program Interface: Review and Consideration by the IRB

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COI Program process: *Overview*

- 'COI investigator' reports Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS)
<http://airs.research.vcu.edu>
- Reviewed by COI Program team in context of awarded proposals and submitted protocols
- FIRs re-reviewed s/p Annual Update and periodically
- COI team can make 'no COI' disposition OR 'Refer to Chair' for further review
- Expedited dispositions of COI or CFI by Chair OR full COI Committee review
- Management plan sent to conflicted investigator for 'acceptance' in the AIRS
- Relevant others/entities notified

Enter the IRB: vis a vis COI assessment

- IRB Staff submits COI review request for all 'COI investigators' on new IRB application and study in progress
 - Change in PI
 - New COI investigator added
 - Continuing review

'COI investigator'

'Investigator' describes any individual, regardless of title, role or position, who is **responsible for the design, conduct, or reporting of research**. By considering an individual's degree of independence relative to the research, the **Principal Investigator on the proposal or protocol designates the individuals who meet the definition of 'Investigator.'**

Consider: When designating 'COI Investigator,' independence and responsibility should be comparable/near comparable to PI.

At minimum, 'COI investigator' is always the PI and the student/trainee investigator of a student project

Enter the IRB: vis a vis COI assessment

- IRB Staff submits COI review request for all 'COI investigators' on new IRB application and study in progress
- 'Yes' response to 'COI question' should be forwarded to COI Pgm (AIRS@vcu.edu)

COI question in electronic RAMS-IRB application: non-definitive assessment feature

The screenshot displays the VCU Office of Research RAMS-IRB application interface. At the top, the VCU logo and 'Office of Research' are visible. Below the header, there is a navigation bar with 'View IRB Study' and a breadcrumb trail: 'Home > Research > COI > Conflict of Interest'. The main content area is titled 'Conflict of Interest' and contains a list of questions. Question 1 asks: 'To the best of your knowledge, do you (as PI) or any other engaged individual hold a financial conflict of interest related to this study?'. It has radio buttons for 'Yes' and 'No'. Question 2 asks: 'If Yes, provide:'. It has two sub-questions: 'Name(s) of the engaged conflicted individual(s)' and 'Brief description of the financial conflict of interests'. Question 3 asks: 'Describe any potential non-financial conflicts of interest for members of the research team that could impact the conduct of the study (if None, please state "None")'. Question 4 asks: 'Describe any institutional conflict of interest with this research that you or any member of the research team may be aware of'. At the bottom, there is a 'Continue' button.

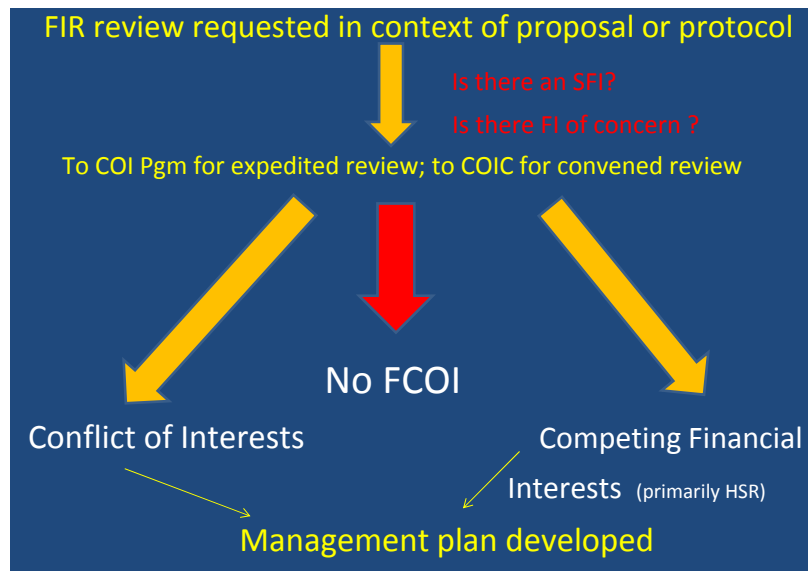
COI Program alerted of 'yes' response by IRB.

As entered by PI, this 'Yes' or 'No' may not be accurate and is not considered a definitive response. May aid COI Pgm assessment.

Enter the IRB: vis a vis COI assessment

- IRB Staff submits COI review request for all 'COI investigators' on new IRB application and study in progress
- 'Yes' response to 'COI question' is forwarded to COI Pgm
- Concurrent review by IRB and COI Pgm
 - IRB Chair invited to join COIC for complicated COI assessment involving HSR; *rare occurrence up til now*

How is a FCOI identified?



VCU COI Policy provisions for HSR (1)

Competing Financial Interest (CFI)

...Financial Interests that **reasonably appear to be related** to the Investigator's Institutional Responsibilities, and **could appear to affect the design, conduct, or reporting of research, primarily human subjects research**. CFI may include, and is not limited to, the following:

- Financial interest(s) in a publicly traded entity that, individually or in aggregate, exceeds \$0 but is **less than \$5,000** on the date of report and during the 12 months preceding an investigator's report (e.g. consulting, honoraria; equity or ownership interest including stock, stock options; compensated travel).
- Unlicensed Intellectual Property to be used within the research
- Licensed Intellectual Property for which royalty payments are distributed through the VCU Intellectual Property Foundation

CFIs are not actionable according to the PHS regulation, so are not termed financial Conflicts of Interest.

Deemed by VCU as warranting attention and internal management.

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- Concurrent review by IRB and COI Pgm
- COI/CFI disposition is reported to IRB.

Communicating COI disposition to IRB

Options:

- ❖ If no COI/CFI for any 'COI Investigator':

To: IRB Panel A/B/C/D:

Email subject: HM_____ PI name – AIRS complete

- ❖ If finding of COI/CFI

To: IRB Panel A/B/C/D, reviewers, Chair

Email subject: AIRS complete; COI/CFI finding on HM_____, name

Content:

- ☐ Nature of FIs leading to finding,
- ☐ Elements of management plan,
- ☐ 'Accepted' management plan attached,
- ☐ COIC or COI Chair recommendation, if any, for IRB **consideration** of additional actions

Enter the IRB: vis a vis COI assessment

- IRB Staff submits COI review request for all 'COI investigators' on new IRB application and study in progress
- 'Yes' response to 'COI question' is forwarded to COI Pgm
- Concurrent review by IRB and COI Pgm
- COI disposition is reported to IRB.
- The research protocol cannot be approved until the IRB/IRB reviewer has **reviewed** the COIC management plan and determined if it sufficient or if further IRB action is needed.

COI Policy provisions for HSR (2)

Reporting of the COI management plan

The financial COI (or Competing Financial Interests) determination and agreed-upon management plan, if relevant, must be reported to....

The Office of Research Subjects Protection for review by the IRB. **The IRB may not minimize the management plan developed by the COIC, but may require additional safeguards to ensure the optimal protection of research subjects.** For example, the IRB may require disclosure in the informed consent form. The research protocol cannot be approved until the IRB has reviewed the COIC management plan.

COI Chair/COIC recommendations to IRB for further action

- Most often, such a recommendation is to consider disclosure language in the ICF
- Recommended language is provided
- Recommended positioning of the suggested language is provided
- Agreeing to it is largely the IRB/IRB reviewers' call based on knowledge of protocol
- Let COI Chair know if recommendation is accepted

COI assessment for central IRB submissions

- Same process: review request for 'COI investigators'
- ORSP notified of all COI/CFI dispositions, other entities as relevant.

Reminder: Research FIR Annual Update

- **Due July 1st**—for all PIs and COI investigators on active or pending proposals or protocols (coincides with new semi-annual SoEI completion requirement)
- No protocol approval until Annual Update completed
- Annual Update required **even if** no changes
- Update period begins 5/10/2015.

VCU resources

- COI in research website
<http://www.research.vcu.edu/coi/>
- VCU IRB Written Policy and Procedure
Evaluating and Managing Investigator Conflicts of Interest
http://www.research.vcu.edu/human_research/irb_wp/VIII-10.htm
- ANY questions or concerns about COI – contact:
 - AIRS@vcu.edu
 - Monika Markowitz, COIC Chair – msmarkow@vcu.edu
or 827-2157.