The IRB – COI Program Interface: Further Review and Consideration by the IRB
Overview of COI Review Process

- The ‘COI Investigator’ completes the Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS).
- The FIR is reviewed by the COI team initially and after any updates in the context of awarded proposals and submitted protocols.
- A disposition is given.
  - The COI team can make a ‘No COI’ disposition or can ‘Refer to Chair’ for further review by the chair or designee.
  - The Chair or designee can make an expedited disposition or ‘Send to COI Committee’ (COIC) for review.
- If it is determined that a conflict exists, the management plan is sent to the conflicted investigator for ‘acceptance’ in the AIRS. Relevant individuals and/or entities are notified.
Annual Update Reminder

• **Due July 1** for all Principal Investigators (PIs) and ‘COI Investigators’ on active or pending proposals/protocols

• No protocol approval until Annual Update completed

• Annual Update **required even if no changes**

• Update period begins in May of each year. The exact date is announced via email from the Vice President of Research and Innovation.
‘COI Investigator’

- Describes any individual, regardless of title, role, or position, who is responsible for the design, conduct, or reporting of research
- Designated by the PI

When considering the designation of *COI Investigator*, independence and responsibility should be comparable/near comparable to that of the PI. The individual’s role in the project, rather than their title, and the degree of independence with which those individuals work should be primary considerations.

At a minimum, the PI and the student/trainee investigator of a student project are designated as *COI Investigators*. 
The Office of Research Subjects Protection (ORSP) uses RAMS-IRB, a database and electronic submission and review system.

Designating **COI investigator** in RAMS-IRB

![Image of RAMS-IRB interface]

1. Indicate all VCU/VCUHS personnel, including the PI, who will be engaged in this study.
2. Identify all non-VCU personnel who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.
3. CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)
Designating *COI investigator* in RAMS-IRB

**Personnel**

1. * Name: 
2. * Is this individual a *COI investigator*? 
   - Yes
   - No
   - Clear
3. * Roles: 
   - Principal Investigator
   - Co/Sub-investigator
   - Medical or Psychological Responsible Investigator
   - Research Coordinator
   - Research Nurse
   - Consultant
   - Research Assistant
   - Pharmacist
   - Statistician
   - Regulatory Coordinator
   - Trainee/Student
   - Other

**Personnel - Non-VCU**

1. * Name: 
2. * Name of Non VCU Institution: 
3. Affiliation: 
   - Non-VCU Affiliate / No Authorization Agreement needed
   - Non-VCU Affiliate / Authorization Agreement needed
   - Independent Investigator / No Independent Investigator Agreement needed
   - Independent Investigator / Individual Investigator Agreement needed
   - Clear
4. * Is this individual a *COI investigator*? 
   - Yes
   - No
   - Clear
5. * Indicate whose COI policy this individual will follow: 
   - VCU COI Policy
   - Non-VCU Affiliate's Institutional Policy
   - Clear
Conflict of Interest (COI)

A COI can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. **COIs generally pertain to financial interests that exceed $5,000 or 3% value.**

**May include the following:**

- Consulting/speaking relationship with the company sponsoring the research
- Serving on the Board of Directors, Scientific Advisory Board, or holding a position in the company sponsoring the research
- Receipt of royalties for technology used in the research
- Equity interest in the company sponsoring the research
Competing Financial Interest (CFI) – VCU Only

CFIs generally pertain to financial interests that exceed $0 or 0% but are less than $5,000 or 3% value.

May include the following:
- Unlicensed intellectual property to be used within the research
- Licensed intellectual property for which royalty payments are distributed through the VCU IPF

Such financial interests in the context of human subjects research will undergo expedited review or will be referred to the COI Committee for full review and possible internal management. CFIs are not reported to the NIH or subject to other requirements of the *PHS ‘Promoting Objectivity in Research’ regulations.*
How is a COI identified?

IRB staff requests COI review for all COI Investigators on protocol

FIRs reviewed in the context of the protocol

Expedited or COI Committee review will determine

No COI
COI/CFI

Management plan put in place; IRB notified

COI Program considers the following:

- Nature of financial relationship(s)
- History and likelihood of continued financial relationship
- The study sponsor or who is providing the product
- Use of experimental product vs. marketed product
- Role of conflicted COI Investigator in protocol
- Built in bias protections in protocol
- Type of IRB review and study
Enter the IRB

- IRB staff submit COI review requests for all COI Investigators for new IRB applications and for studies in progress when:
  - There is a PI change.
  - A new COI investigator has been added.
  - The studies are undergoing continuing review.

- IRB staff alert the COI Program via email (AIRS@vcu.edu) when the RAMS-IRB ‘Conflict of Interest’ question is answered as ‘Yes’.
  - The answers provided here are not considered definitive responses as they may not be accurate, but they can aid COI assessment.

- IRB Chair may be invited to join COIC for complicated COI assessment involving HSR (a rare occurrence to date)
The COI Program is alerted of a ‘Yes’ response by IRB.
Enter the IRB

• For external IRB submissions, **sequential review** by COI Program and IRB
  - COI assessment is completed before sending the protocol to the external IRB
  - Protocols submitted to external IRBs will be reviewed for the initial submission to RAMS-IRB.

• For all other protocols, **concurrent review** by COI Program and IRB
  - Protocols will be reviewed for initial submission to RAMS-IRB and when undergoing continuing review.

• COI investigators at external institutions that are deferring to the VCU IRB are subject to COI assessment and management either by their home institution or VCU COI assessment per [VCU COI Policy](#) requirements.
Communicating COI Disposition to IRB

A COI or CFI that has been managed by the COIC is forwarded to the IRB with an explanation of the conflict and management plan as well as recommendations, if any, for IRB actions.

Options:

- If no COI/CFI for all COI Investigators on the protocol:
  
  To: IRB coordinator  
  Email subject: HM______, PI name – AIRS complete

- If finding of COI/CFI

  To: IRB coordinator, Susan Kimbrough  
  Email subject: COI/CFI finding on HM______, PI name – AIRS complete  
  Content:

  - Nature of interests leading to finding  
  - Elements of management plan  
  - Additional actions, if any, recommended by COIC or COI Chair for IRB consideration  
  - ‘Accepted’ management plan attached
Management Plan Example

Subject: Finding of Conflict of Interest
HM00000000: ______________________________
Sponsor: ___________________________
PI: ____________, ___

The VCU Conflict of Interests Committee (COIC) discussed your reported financial relationships at their (date) meeting in the context of the above-referenced research project.

On the basis of the provided information, the COIC reviewer(s) concluded that there is an appearance of a financial conflict of interest (COI) as a result of your aggregate payment in the last 12 months that exceeds $5,000 for consulting activities with ____________, the company sponsoring this research.

**To manage your conflicting financial interest and its appearance:**

1. Disclose your consulting relationship with the sponsor in submissions for publication and/or presentation, consistent with journal and professional disclosure requirements.
2. The managed COI should also be fully disclosed to any personnel working with you on these projects (i.e. colleagues, administrative staff, students, and trainees) by sharing this management plan with the study team.

The COI management plan remains in place for the duration of the sponsored project plus one year post-closure of the study at VCU. If this management plan is acceptable to you, execute the activity "Review Management Plan" in the AIRS. An annual update regarding how this management plan was fulfilled is due to the COIC within one year upon request.

Thank you in advance for your cooperation with VCU’s COI in Research process. Please contact the COI Program at 827-2156 or AIRS@vcu.edu if you have any questions.

cc: ORSP, ___ (PI)
COI Chair/COIC Recommendations to IRB for Further Action

• Most often involves recommended ICF disclosure language to consider
  – 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 and ‘risk/disclosure’ assessment
• The COI Chair or designee should be informed whether the recommendation is accepted
Reporting of the COI Management Plan

From the VCU COI in Research Policy:

The COI/CFI determination and agreed-upon management plan must be reported to the ORSP 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/IRB reviewer has reviewed the COIC management plan and determined if it sufficient or if further IRB action is needed.
Reporting of the COI Management Plan

From the VCU IRB Written Policy and Procedure: Evaluating and Managing Investigator Conflicts of Interest:

• If the protocol in question is a full board study, and the Chair and/or reviewers agree that additional IRB action to protect research participants from risk or harm due to potential bias is warranted, the convened IRB Panel must review any recommended changes within IRB purview prior to the release of the IRB approval letter.

• If the protocol is exempt or expedited review, the single reviewer and Chair/designee review the COIC management plan and recommendations for further IRB action. Any required changes to the protocol as a result of the COIC determination are reviewed and approved according to exempt and expedited review procedures before the release of the IRB approval letter.
Resources

**COI Program website**

**VCU 'Conflict of Interests in Research' policy**


**VCU IRB Written Policy and Procedure: Evaluating and Managing Investigator Conflicts of Interest**

For questions or concerns regarding COI, please contact the COI Program at AIRS@vcu.edu or Cristen Jandreau, Ph.D. at cbjandreau@vcu.edu or 827-2156.