VCU Research Financial Conflict of Interest (FCOI) Management Matrix

Directions: The middle column lists types of competing or conflicting financial interests an ‘investigator’ may have in an entity that is related, or could appear to be related, to the research to be conducted under a proposed project. An ‘investigator’ is an individual who has responsibility for the design, conduct, or reporting of research, regardless of title or role. The column on the left (human subjects research) and the column on the right (non-human subjects research) list management options depending on the circumstances of conflicting interests.

Note: Using the matrix as a guide, the COI Committee makes COI determinations on a case-by-case basis. The IRB/IACUC may require additional management that pertains to subject protections and welfare. Advance discussion about COI management is encouraged. Contact the COI team at AIRS@vcu.edu.

Definitions:

<table>
<thead>
<tr>
<th>Baseline Management</th>
<th>Disclosure in submissions for publication/presentation and to students, trainees, and, depending on type of research, co/sub-investigators. Applies to all managed research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent Form (ICF)</td>
<td>Explains to potential participants the nature of the research project; why they are candidates for the research; what risks, benefits, and alternatives are associated with the research; and what rights they have as research subjects.</td>
</tr>
<tr>
<td>Competing Financial Interest (CFI)</td>
<td>Issued for financial interests &lt;$5,000 at the discretion of the COI Committee depending on the type of research and the conflicted investigator’s role. Subject to internal management and is not reportable to funding agencies.</td>
</tr>
<tr>
<td>Institutional Conflict of Interest (ICOI)</td>
<td>A situation in which the financial interests of the University or financial interests of covered members exceeding $100,000 might influence or reasonably appear to affect institutional activities involving research. Such influence can emanate from individuals among VCU leadership who hold positions of trust, as well as within the university itself, its entities, and its holdings.</td>
</tr>
<tr>
<td>State-prohibited Contract</td>
<td>Equity interest ≥3% value, ≥$5,000 annual income (real or anticipated), or significant investment levels may pose a state-prohibited contract under § 2.2-3106 of the Code of Virginia State and Local Government Conflict of Interests Act, requiring recommendation of a C.8. exception.</td>
</tr>
</tbody>
</table>

Possible COI management plan scenarios (subject to individual circumstances)

Human Subjects Research

Baseline management and recommended disclosure in ICF. Depending on circumstances, additional management may be necessary or may not be amendable.

Non-human Subjects Research

Baseline management. Additional management may be necessary if the PI is promoting the company’s product used in the research and/or the compensation is substantially > $5,000.

Consulting/speaking relationship or scientific advisory board membership with company sponsoring the research (or providing ‘in-kind’ sponsorship, e.g. study drug or device)

Possible CFI depending on type of research and the conflicted investigator’s role
* Not reportable to the NIH
Based on the Financial Interest Report, the investigator has indicated:

**Human Subjects Research**

- **Payment ≥ $5,000 in aggregate/year?**
  - YES
    - Paid Position?
      - YES
        - Recuse self from decision making about research funding to VCU
      - NO
        - PI or co/sub-investigator or supervising designated PI?
          - NO
            - Baseline management and recommended ICF disclosure*
          - YES
            - Depending on research, restrictions including recruitment considerations may apply
            - Alternate PI?
              - YES
                - No recruiting/enrolling; no access to identifiable data; COI management oversight; 'safe person' for communications with peers/students and research subjects
              - NO

- **Transfer project to a non-conflicted PI?**
  - YES
    - PI?
      - YES
        - Divesture to maintain investment < $5,000 for duration of study
      - NO
        - Baseline management and recommended ICF disclosure
  - NO
    - Possible CFI depending on type of research and the conflicted investigator's role. Recommended ICF disclosure
    - Remove self from study

**Non-human Subjects Research**

- **Payment ≥ $5,000 in aggregate/year?**
  - YES
    - Officer or Director for a company or organization sponsoring the research (paid or unpaid)
      - YES
        - Recuse self from decision making about research funding to VCU
      - NO
        - Paid?
          - YES
            - Baseline management
          - NO
            - Publication/abstract oversight; COI management oversight; 'safe person' for communications with peers and students
  - NO
    - Baseline management
    - Transfer project to a non-conflicted PI
    - Divesture to maintain investment < $10,000 and baseline management

**Equity Interest in a public company sponsoring the research (excluding interests in mutual funds) that is directly managed by the individual**

- **≥3% value or ≥ $10,000 in aggregate/year (real or anticipated)?**
  - YES
    - PI?
      - YES
        - Baseline Management
      - NO
        - Transfer project to a non-conflicted PI
        - Divesture to maintain investment < $10,000 and baseline management
  - NO
    - Baseline management

* Not reportable to the NIH

** May represent a state-prohibited contract requiring recommendation of a C.8. exception, which is generally not allowed if the award to VCU is to be subcontracted to the company
** May represent a state-prohibited contract requiring recommendation of a C.B. exception, which is generally not allowed if the award to VCU is to be subcontracted to the company
To mitigate COI, all industry-sponsored training grants should be submitted through the Office of Sponsored Programs via a non-conflicted PI.