Training on Conflicts of Interest in Research

Office of Research Integrity and Ethics
Conflicts of Interest in Research Program
Introduction

• This required Conflict of Interest (COI) in Research training must be completed and submitted in the VCU Activity and Interest Reporting System (AIRS).

• Training will address the following:
  – *Promoting Objectivity in Research* (revised 2011 Public Health Service (PHS) regulations)
  – VCU *Conflicts of Interest in Research policy*
  – VCU *Institutional Conflicts of Interest in Research – INTERIM policy*

• PHS regulations require training prior to engaging in research, at least every 4 years, and immediately after the following circumstances:
  – An investigator is new to the institution;
  – The VCU *COI in Research* policy is revised in a manner that affects the requirements of investigators; or
  – The institution finds that an investigator is not in compliance with the VCU *COI in Research* policy or issued management plan.
On August 25, 2011, the Department of Health and Human Services (DHHS) released a final rule that revised and strengthened the 1995 PHS rules for Promoting Objectivity in Research. The final rule places the onus on the institution for identifying and managing financial COI.

Highlights from the final rule:

- The de minimus threshold for SFI is $5,000.
- COI training is required for all investigators every 4 years (at a minimum).
- The investigator must report compensated travel.
- The institution has the responsibility for determining whether a SFI constitutes a financial COI (FCOI).
- Upon an appropriate request of information from the public, an investigator’s managed COI will be disclosed within 5 days.
- PHS and DHHS oversee institutional compliance.
Key Definitions

- **COI Investigator**
  - A designation determined by the PI that describes any individual (regardless of title, role, or position) who is responsible for the design, conduct, or reporting of research.

- **Institutional responsibilities**
  - An investigator’s professional responsibilities on behalf of the institution, which may include research, research consultation, teaching, professional practice, and service on committees.

- **Significant Financial Interest (SFI)**
  - Financial interests that reasonably appear to be related to the investigator’s institutional responsibilities; could appear to directly and significantly affect the design, conduct, or reporting of research; and generally include interests in a public entity that exceed $5,000, any financial or ownership interest in a non-publicly traded entity, and royalties from intellectual property (IP).

- **Financial Interest Report (FIR)**
  - The report in the VCU AIRS that contains reported financial interests held by the investigator and any member of his or her immediate family.
COI in Research

• A COI can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

• Potential COI are not unusual in a modern academic setting but must be addressed in order to provide transparency and to protect research integrity.
  – Financial or non-financial interests can yield conscious or subconscious bias in the conduct and/or interpretation of research.
  – Financial COI can simply present an appearance of compromising an investigator's professional judgment in conducting or reporting research.
  – While financial interests with outside entities are not intrinsically unethical, they threaten research integrity if not reported, identified, and managed.
  – Unidentified COI can be especially problematic in human subjects research if the investigator’s objectivity appears to be compromised.
VCU COI in Research Policy

• The COI in Research policy is informed by:
  – Federal regulation: ‘Promoting Objectivity in Research’ (42 CFR Part 50 Subpart F)
  – State law: State and Local Government Conflict of Interests Act (Code of Virginia § 2.2-3100 - 2.2-3131)

• VCU-specific COI policies and processes:
  – Electronic reporting of financial interests in the AIRS for all those deemed as COI Investigators (including subrecipients)
  – Reporting of financial interests and their research relatedness (including travel) in the AIRS initially, annually, and within 30 days of acquiring a new financial interest
  – Greater emphasis on policy compliance and consequences of non-compliance

• This policy requires all COI Investigators on proposals or protocols, regardless of research funding status or funding source, to report financial interests and their research relatedness via the AIRS.
VCU Institutional COI in Research Policy

• An institutional conflict of interest (ICOI) is a situation in which the financial interests of the university or its covered members might 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.

• Financial interests include:
  – Gifts, pledges, or payments (including royalties) to the university that meet or exceed $100,000
  – Equity, ownership, or financial interests held by the university that exceed $50,000 in publicly traded companies or interests of any amount in a non-publicly traded entity
  – Business interests, licenses, or revenue held by a covered member that exceed $10,000 or ownership interests exceeding 3% of the total equity in each outside firm or business
  – Gifts, salary, wages, or payments received by the covered member that exceed $10,000

• Financial interests of covered members and university entities will be disclosed annually and updated throughout the year.
Reporting Financial Interests

• **Reported financial interests include:**
  – Officer, Director, and Advisory Board Positions, whether paid or unpaid
  – Additional salary or other payments for services (e.g. compensated travel, consulting fees, honoraria, seminars, lectures, or other teaching engagements) from an entity other than VCU
  – Equity interests (e.g. stock, stock options, or other ownership interests)
  – Intellectual property (e.g. inventions, patents, and copyrights) and its related income

• **Reported financial interests do not include:**
  – Salary, reimbursement, or remuneration originating from VCU, with the exception of payments from the VCU Intellectual Property Foundation (IPF);
  – Grants/contracts or gifts/in kind materials processed by OSP; and
  – Travel that was paid by VCU or by a project processed through OSP.
Reporting Financial Interests

• Each investigator reports financial interests held by him or herself or any member of his or her immediate family.
  – *Immediate family* means the investigator’s spouse and any child who resides in the same household as the investigator and who is a dependent of the investigator.

• **When to report financial interests:**
  – Annually (annual reporting begins May 10th each year and is due by July 1st)
  – Within 30 days of acquiring a new financial interest
Significant Financial Interests (SFI)

• SFI appear to be reasonably related to the investigator’s institutional responsibilities and could appear to directly and significantly affect the design, conduct, or reporting of research.

• **SFI include the following:**
  – Financial interest in a publicly traded entity (e.g. consulting fees or honoraria; equity interest including stock or stock options) that, individually or in aggregate, exceeds $5,000 in the last 12 months
  – Any financial or ownership interest in a non-publicly traded entity (e.g. a start up company)
  – Licensed IP in which royalty payments have been received from an entity other than VCU
  – NOTE: Travel in combination with other financial interests may be a SFI.
Competing Interest (CI) – VCU Only

• CI is an internal designation for interests that do not rise to the level of COI but are deemed by VCU to warrant attention and internal management; they are not reportable or actionable according to PHS regulation. Such financial interests in the context of human subjects research will be referred to the COI Committee for expedited or full review and possible internal management.

• CI may include:
  – Financial interests in a publicly traded entity (e.g. consulting fees or honoraria; equity interest including stock or stock options) that, individually or in aggregate, exceeds $0 but is less than $5,000 during the 12 month period preceding COI review
  – Unlicensed IP to be used within the research
  – Licensed IP for which royalty payments are distributed through the VCU IPF
How is a COI/CI Identified?

1. Financial interests reported
2. COI in Research Program requested to review FIR in the context of the proposal or protocol
3. Expedited or COI Committee review will determine
   - No COI
   - COI/CI
Management Plans

• If it is deemed that a COI Investigator has a COI/CI that requires management after expedited or COI Committee review, he or she will be issued a management plan.

• COI investigator responsibilities:
  – Review each issued management plan, request any changes, and accept the plan after an agreement has been reached. Once the management plan has been accepted, any holds on funding or protocol approvals related to the plan will be released.
  – Comply with all terms, conditions, and actions required under the management plan. The investigator must respond to all requests for information, meetings, or reports regarding the university’s responsibility to monitor compliance with the plan.

• Note that preemptive discussion about a foreseen COI is welcome. Contact AIRS@vcu.edu to begin a conversation with the COI team.
AIRS

- The AIRS is a secure Research Administration Management System (RAMS) that contains reported financial interests and can be entered via the Office of Research and Innovation website through the RAMS & VCUeRA tab.
  - If outside VCU, use the VPN to enter the AIRS.

- Each investigator enters his or her own financial interests into the AIRS by logging in with their eID & password.

- The following slides will show screenshots of basic AIRS components.
Home Screen

Welcome to the VCU Activity and Interest Reporting System (AIRS)

Click your name below to access the Financial Interest Report (FIR) Workspace.

If at any point you need assistance in using this system, please click here to be taken to the Help webpage.

<table>
<thead>
<tr>
<th>My Financial Interest Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Financial Interest Report for [your name]</td>
</tr>
</tbody>
</table>
Investigator FIR Page

Click the "Edit Financial Interest Report" button under My Financial Interest Report Forms and follow the instructions on your screen.

Once finished, click the "Finished Updating My Financial Interest Report" activity.
### Financial Interests

#### 1.0 Officer, Director, and Advisory Board Positions
- In the past 12 months, have you or a member of your immediate family served as an officer, director, or advisory board member?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 2.0 Stocks, Bonds, and Options
- In the past 12 months, have you or a member of your immediate family owned stocks, bonds, or options that you directly control?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 3.0 Outside Professional Activities and/or Travel
- In the past 12 months, have you or a member of your immediate family received remuneration outside of VCU/VCUHS for consulting, other outside professional activities, or travel related to your capacity as a VCU/VCUHS employee?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 4.0 Non-VCU/VCUHS Salary or Other Income
- In the past 12 months, have you or a member of your immediate family received a salary or other income outside of VCU/VCUHS?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 5.0 Business Ownership
- In the past 12 months, have you or a member of your immediate family owned or operated a business?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 6.0 Grants Outside of VCU, Gifts, or In Kind Materials
- In the past 12 months, have you or a member of your immediate family received a grant outside of VCU, a gift, or in-kind material to support your role at VCU?
  - [ ] Yes
  - [ ] No
  - [ ] Clear

#### 7.0 Intellectual Property
- Do you or a member of your immediate family own or have an inventive interest in any intellectual property (e.g., inventions, patents, tangible research materials, copyrights, etc.)?
  - [ ] Yes
  - [ ] No
  - [ ] Clear
### Outside Professional Activities and/or Travel Details

1. List the remuneration you or a member of your immediate family has received in the past 12 months for consulting, other outside professional activities, and/or travel related to your capacity as a VCU/VCUHS employee:

<table>
<thead>
<tr>
<th>No.</th>
<th>Payer Name</th>
<th>Activity Types</th>
<th>Activity Type - Other Payer Type</th>
<th>Payment Type</th>
<th>Payment Type - Other Travel Destination</th>
<th>Duration of Travel</th>
<th>Payment Amount</th>
<th>Payment Date</th>
<th>Related Interest Explanation</th>
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<td>Serving in office or on committee for an academic/professional society or nonprofit organization</td>
<td>Non-Profit Organization</td>
<td>Travel Reimbursement</td>
<td>Honorarium</td>
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<td></td>
<td></td>
<td></td>
<td>1000</td>
<td>4/5/2017</td>
</tr>
</tbody>
</table>
Submitting your FIR

• To submit your FIR, check the box before clicking the ‘Finish’ button.
When is a FIR Reviewed?

- Upon annual update by the investigator
- Prior to protocol approval and/or prior to award processing
  - Review request sent to COI in Research Program for each COI Investigator’s FIR to be assessed for COI/CI in the context of the research
  - FIR must be updated within the most recent update period
Reasons an Investigator May be Contacted

- Update of FIR needed within AIRS
- Question regarding:
  - Unreported financial interest in AIRS (based on OPA comparison or other information)
  - Relatedness of a financial interest to the research project being reviewed
  - Details/clarification of a financial interest
  - Use of intellectual property in a research project
- Issued a management plan
- Follow-up on a previously issued management plan
- Non-compliance with a management plan
COI in Research Program Responsibilities

- Review FIR submissions to identify COI/CIs
- Develop and implement management plans for COI/CIs
- Report FCOI to PHS sponsors, other federal agencies as required, and other sponsors upon request
- Verify with subrecipient institutions the existence of a policy that meets the PHS *Promoting Objectivity in Research* requirements; if none, subrecipients use the VCU AIRS
- Review unreported/unreviewed financial interests and, if necessary, implement a management plan within 60 days
- Upon a determination of non-compliance:
  - The research project and the investigator’s activities are retrospectively reviewed within 120 days of the discovery of non-compliance with the VCU *COI in Research* policy to determine if there was bias in the design, conduct, or reporting of research.
  - If bias is found, the PHS sponsor is notified promptly and a mitigation report is submitted.
A COI requiring management can arise in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

Report all financial interests in the AIRS on an annual basis and within 30 days of acquiring a new financial interest or additional remuneration for a reported interest.

– Interests should be reported for the last 12 months from the date of the report.

Preemptive discussion about a foreseen COI is encouraged. Contact AIRS@vcu.edu to begin a conversation with the COI team.
Resources

- **Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought** (or Promoting Objectivity in Research) regulations (42 CFR Part 50)
- **Responsible Prospective Contractors** regulations (45 CFR Part 94)
- **Conflict of Interest** – National Science Foundation (NSF) Rules
- **21 CFR 54** – FDA regulation for financial disclosure by clinical investigators
- **State and Local Government Conflict of Interests Act** (Code of Virginia § 2.2-3100 - 2.2-3131)
- VCU **Institutional Conflicts of Interest in Research – INTERIM** policy
- VCU **Conflicts of Interest in Research** policy
- VCU **Guidelines and Procedures for Disclosure, Approval and Reporting of Outside Professional Activities** policy
- VCU Institutional Review Board (IRB) Written Policy and Procedure: [VIII-10 Evaluating Investigator and other Potential Conflicts of Interest](#)
- VCU **COI in Research website**

For additional information, [CITI](#) offers a COI mini-course. Log in using your CITI username and password. Add the COI course to your menu.
Questions about completing the FIR or about the information presented? Please visit the [COI website](http://example.com) or contact the COI in Research Program at [AIRS@vcu.edu](mailto:AIRS@vcu.edu).