Who is a *COI Investigator* for AIRS reporting purposes?

Office of Research Integrity and Ethics
Conflict of Interest in Research Program
COI Investigator

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

• An individual with the level of independence and responsibility comparable to that of the PI should be designated as a COI Investigator.
  – 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.

• COI Investigators must complete a Financial Interest Report (FIR) in the Activity and Interest Reporting System (RAMS-AIRS).
  – The AIRS is a secure management system for reporting interests, while the FIR is the SmartForm in the AIRS that contains reported interests.
Who is a COI Investigator?

Note: Not all individuals on a proposal/protocol are COI Investigators.

Yes
– PI/co-PI on proposals or protocols

Likely
– Co/sub-investigator
– Subrecipient investigator with responsibilities comparable to the VCU PI
– Key/senior personnel
– Project manager/director
– Medical investigator
– Research staff authorized to make independent decisions without PI consultation
– Post-doc
– Graduate student if serving as ‘functional’ PI on protocol

Unlikely
– Anyone under direct supervision and with limited/no decision-making authority (e.g. research staff, students)
– Personnel who support the research enterprise (e.g. investigational pharmacists, lab technicians)
– Anyone other than the PI on a training, practice, or resource grant
– Engaged community members recruiting or surveying participants
VCU COI in Research Policy

- The VCU *Conflicts of Interest in Research* policy applies to COI Investigators on all research, including research that is:
  - Public Health Service (PHS)-funded (e.g. NIH)
  - Funded by a non-NIH federal entity
  - Funded by a state agency
  - Funded by industry or any for-profit entity
  - Funded by any non-profit entity
  - Funded internally
  - Not funded at all

- The policy also applies to research involving adherent subrecipient institutions and non-VCU collaborators (as well as when VCU is a subrecipient).
Subrecipients and Non-VCU Collaborators

• The VCU Office of Sponsored Programs (OSP) will verify with non-FDP Expanded Clearinghouse subrecipient institutions whether the VCU *COI in Research* policy or the COI policy of the subrecipient institution will apply to its investigators.
  – If the subrecipient institution agrees to abide by VCU’s *COI in Research* policy, the subrecipient PI must complete the VCU [Subrecipient Interest Disclosure Form](#) prior to proposal submission to NIH, NSF, or any other sponsors who have adopted the federal financial disclosure requirements.
  – Each individual identified as a COI Investigator on this form will be required to fill out the disclosure section.

• Prior to award dispersal or protocol approval, COI Investigators external to VCU must log in to the AIRS to complete their FIR.
  – COI Investigators external to VCU who are deferring to VCU’s COI in Research policy must report financial interests, as described herein, except *they are to only include interests that are directly related to their work for VCU.*
  – Note that emails from the AIRS go to the individual’s @vcu.edu email account (i.e. jdoe@vcu.edu), which cannot be changed. It is recommended that emails from this account be forwarded to a favored one if that is preferred.
Reporting Interests

• Each COI Investigator reports financial interests held by themselves and any member of their immediate family in the AIRS.
  – *Immediate family* means the investigator’s spouse and any person who resides in the same household and is a dependent of the investigator.

• When and what to report?
  – Initially and annually beginning May 10th (notification email will be sent out through the AIRS)
  – Include interests for the last 12 months from the date of the report and their research relatedness, if any, to all proposed or ongoing research

• When to update?
  – Within 30 days of acquiring:
    • A new interest or an additional interest in a previously reported entity
    • New IP that has been disclosed to VCU Innovation Gateway
    • New research relatedness with any reported interest
The PHS *Promoting Objectivity in Research* regulations and VCU *COI in Research* policy require COI training for all COI Investigators at least every 4 years. Investigators currently within the 3-4 year time frame will be directed to complete the short training module preceding their annual update.

Successful training completion will be documented on the FIR workspace.
What do PIs need to do?

- Determine if personnel listed on grant proposals or IRB/IACUC protocols qualify as COI Investigators
  - Note that in all the RAMS systems, the PI is always a COI Investigator. Personnel on the study must be designated as COI Investigators, as appropriate.

- Notify all those designated as COI Investigators on pending proposal/protocol submissions to ensure their FIRs are current (updated on an annual basis beginning May 10\textsuperscript{th}, at a minimum)
  - Proposal submissions, protocol approvals, and award dispersals will not move forward until all FIRs are current.

- Work with OSP and the IRB and IACUC offices regarding subrecipients and non-VCU collaborators
Resources

- **AIRS Guidance and Training**
- **VCU policy**: *Conflicts of Interest in Research*
- **VCU OSP form**: *VCU Entity Form for non-FDP Expanded Clearinghouse Subrecipients*
- **VCU COI in Research Program form**: *Subrecipient Interest Disclosure Form*
- **Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought** (or *Promoting Objectivity in Research*) PHS regulations (42 CFR Part 50)
- **Responsible Prospective Contractors** PHS regulations (45 CFR Part 94)

To access the AIRS, RAMS-SPOT, RAMS-IRB, or RAMS-ACUP, visit the [RAMS Systems](#) page. For technical help with RAMS Systems, contact [erahelp@vcu.edu](mailto:erahelp@vcu.edu). If outside VCU, set up and access [RamsVPN](#). For help accessing RamsVPN, contact [itsc@vcu.edu](mailto:itsc@vcu.edu).

Questions? Visit the [COI in Research](#) website or contact the COI in Research Program at [AIRS@vcu.edu](mailto:AIRS@vcu.edu).