



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

COI Training

- 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.

History	Comments	Meetings	Archive
Activity			
	Financial Interest Report Updated		
	COI Training Completed 		

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 10th, 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. If outside VCU, set up and access [RamsVPN](#). For help accessing RamsVPN, contact itsc@vcu.edu.

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