



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

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

COI Investigator

Describes any individual (regardless of title, role, or position) who is responsible for the design, conduct, or reporting of research

- When designating *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.
- COI Investigators must complete a Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS). The AIRS is a secure, electronic data entry system for reporting financial interests, while the FIR is the report that contains these financial interests.

Who is a COI Investigator?

Might be a COI Investigator

- PI on proposal/protocol**
- Co-PI**
- Co/sub-investigators*
- Key/senior personnel*
- Project manager/director*
- Student (usually graduate or trainee) who is 'functional' PI on protocol*
- Medical investigator*
- Research staff authorized to make independent decisions without PI consultation*
- Consultant who will make decisions about design, conduct, or analysis/reporting*

** always * very likely

Probably not a COI Investigator

- Students under the direct supervision of PI/co-PI or co/sub-investigator
- Research staff, including engaged community members, under direct supervision (i.e. they must consult with PI, have no/limited independent decision making authority)
- Research-related personnel whose jobs support the research enterprise (e.g. investigational pharmacists, lab technicians, CRSU staff)
- Anyone other than the PI on a training, practice, or resource grant

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

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/business
 - 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 subrecipient institutions whether the VCU *COI in Research* policy or the financial COI policy of the subrecipient institution will apply to its investigators who are collaborating with VCU investigators.
 - At a minimum, PIs at subaward institutions are COI Investigators.
 - Prior to submission of a PHS-sponsored proposal (or proposal for a sponsor who is adherent with the PHS [Promoting Objectivity in Research](#) regulations), the subrecipient completes the [VCU Subrecipient Interest Disclosure Form](#).
- Designation of *COI Investigator* for non-VCU collaborators depends on whether the level of responsibility and independence is near comparable to the PI.
 - For example, engaged community members recruiting or surveying participants are accountable to the PI and as such are likely not COI Investigators.
 - However, an investigator at a collaborating institution with responsibilities comparable to the VCU PI is likely a COI investigator.

What do PIs need to do?

- Determine if personnel listed on grant proposals or IRB/IACUC protocols qualify as COI Investigators
- Notify all those designated as COI Investigators on the pending proposal/protocol submission to ensure their FIRs are current (updated on an annual basis by July 1st and within 30 days of acquiring a financial interest)
- Work with OSP and the Office of Research Subjects Protection (ORSP) regarding subrecipients and non-VCU collaborators

Designating *COI Investigator* in RAMS-SPOT

- The *COI Investigator* designation is made in the Personnel section of RAMS-SPOT, the OSP proposal submission and review system.

Personnel

1. * Is this a multi-PI Submission:

Yes

No

[Clear](#)

2. * Select all named VCU personnel, including the PI, who will be involved in this proposal:
(NOTE: Do not include VCU Health Systems personnel. TBD persons will be included in the budget only.)

Last Name	First Name	Department	Role	(Other)	Key	COI
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NOTE: The PI is always a COI Investigator. Personnel added to the study must be designated as COI Investigators, as appropriate.

Designating *COI Investigator* in RAMS-SPOT

Add Institutional Proposal Staff

1. * Select Individual:

2. * Select Project Role:

If "Other (Specify)" selected, enter the role below:

3. * This individual is a:

- Senior/Key Person
- Other Significant Contributor
- Non-Key Person

[Clear](#)

4. * Is this individual a COI investigator:

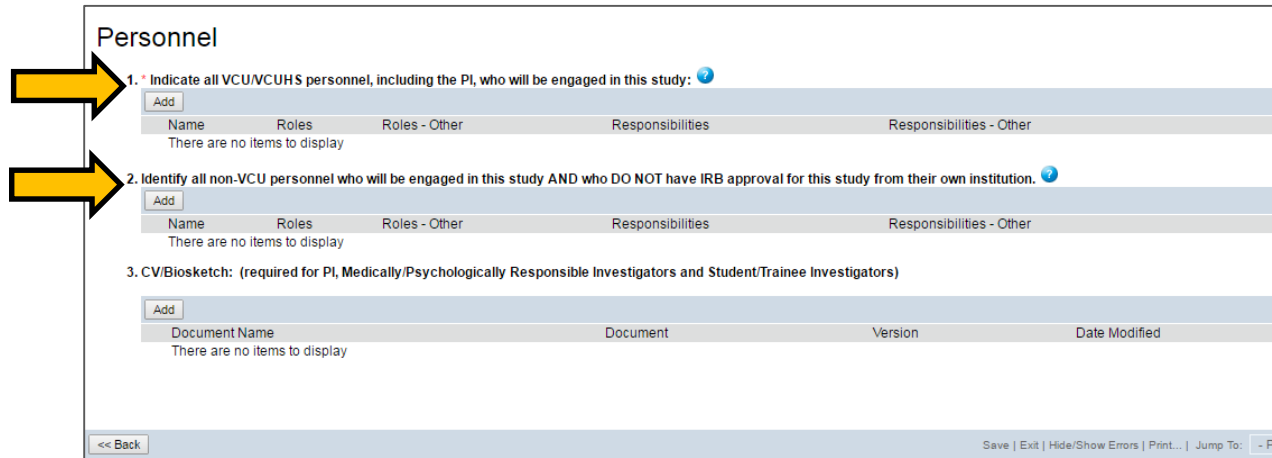
- Yes
- No

[Clear](#)




Designating *COI Investigator* in RAMS-IRB


- The *COI Investigator* designation is made in the Personnel section of RAMS-IRB, the IRB protocol submission and review system.



Personnel

1. * Indicate all VCU/VCUHS personnel, including the PI, who will be engaged in this study: 

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other
There are no items to display				

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. 

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other
There are no items to display				

3. CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)

Document Name	Document	Version	Date Modified
There are no items to display			

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Designating *COI Investigator* in RAMS-IRB

Personnel

1. * Name: [Select...](#)

2. * Is this individual a 'COI Investigator'? [?](#)

Yes
 No
[Clear](#)

3. * Roles: [?](#)

<input type="checkbox"/>	Principal Investigator
<input type="checkbox"/>	Co/Sub-Investigator
<input type="checkbox"/>	Medical or Psychological Responsible Investigator
<input type="checkbox"/>	Research Coordinator
<input type="checkbox"/>	Research Nurse
<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Research Assistant
<input type="checkbox"/>	Pharmacist
<input type="checkbox"/>	Statistician
<input type="checkbox"/>	Regulatory Coordinator
<input type="checkbox"/>	Trainee/Student
<input type="checkbox"/>	Other

Personnel - Non-VCU

1. * Name:

2. * Name of Non VCU Institution:

3. Affiliation: [?](#)

<input type="radio"/>	Non-VCU Affiliate / No Authorization Agreement needed
<input type="radio"/>	Non-VCU Affiliate / Authorization Agreement needed
<input type="radio"/>	Independent Investigator / No Independent Investigator Agreement needed
<input type="radio"/>	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: [?](#)

<input type="radio"/>	VCU COI Policy
<input type="radio"/>	Non-VCU Affiliate's Institutional Policy

[Clear](#)


Designating *COI Investigator* in RAMS-ACUP

- The *COI Investigator* designation is made in the Personnel & Qualifications section of RAMS-ACUP, the IACUC protocol submission and review system.

Study Staff

Select all study staff and indicate their role(s), procedure training, qualifications and experience: ?

Name	Roles	Procedures	Experience	COI	Receive AHI emails
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Reporting Financial Interests

- Each COI Investigator reports financial interests held by him or herself or any member of his or her immediate family (spouse and any child residing in the same household as the investigator who is a dependent of the investigator).
- **When and what to report?**
 - Initially and annually by July 1st (notification email will be sent out)
 - Include financial interests for the last 12 months and their research relatedness, if any, to all proposed or ongoing research
- **When to update?**
 - Within 30 days of discovering or acquiring a new financial interest OR additional remuneration for a reported interest
 - May need to update research relatedness for new proposals/protocols based on existing financial interests

Training Renewal

- The PHS *Promoting Objectivity in Research* regulations and VCU policy require COI training for all investigators at least every 4 years. Investigators currently within a 3-4 year time window will automatically be prompted to complete the short training module preceding their annual update.
- Training completion is automatically documented in the investigator's FIR page.

History	Comments	Archive	Documents	Additional Information	Reviews	Management Plans	Snapshot
Activity		Author				<input checked="" type="checkbox"/> Activity Date	
	COI Training Completed					6/14/2016 1:50 PM	
	Annual Financial Interest Reporting Begins	Administrator, System				5/10/2016 3:49 AM	
	Financial Interest Report Opened for Editing	Administrator, System				5/10/2016 2:59 AM	
	COI Training Expired	Administrator, System				5/9/2016 8:07 AM	
	COI Training Completed					9/13/2012 1:51 PM	

Resources

- [Instructions for using the AIRS](#)
 - VCU [Conflicts of Interest in Research](#) training
 - VCU [Conflicts of Interest in Research](#) policy
 - [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)
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- To access AIRS, RAMS-SPOT, RAMS-IRB, or RAMS-ACUP, visit the [RAMS & VCUeRA Systems](#) page.
 - For technical help with the RAMS Systems, contact eRAHELP@vcu.edu.
 - For instructions on how to access VCU VPN, visit the [VCU Technology Services RamsVPN](#) page.
 - For help accessing VCU VPN, contact itsc@vcu.edu.

Questions about completing the FIR or about the information presented? Please visit the [COI website](#) or contact the COI in Research Program at AIRS@vcu.edu.