

Who is a 'COI investigator' for purposes of reporting in AIRS?

Define 'COI investigators'

'Investigator' describes any individual, regardless of title, role or position, who is responsible for the design, conduct, or reporting of research. By considering an individual's degree of independence relative to the research, **the Principal Investigator on the proposal or protocol designates the individuals who meet the definition of 'Investigator.'**

Consider: When designating 'COI Investigator,' independence and responsibility should be **comparable/near comparable to PI.**

Designated **'investigators'** enter the AIRS to **complete a Financial Interest Report(FIR).**

NIH - Who is a 'COI Investigator'?

NIH defines an 'Investigator' as:

the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.

Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#

Who is a 'COI investigator'?

(not all individuals on a proposal/protocol are 'COI investigators'!)

MIGHT BE A 'COI INVESTIGATOR'

- PI on proposal/protocol **
- Co-PI **
- Co- or sub-Investigators *
- Key/Senior Personnel on proposal *
- Project manager/director *
- Student (usually graduate/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/Co-I
- 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, eg. Investigational pharmacists, lab technicians, CRSU staff
- Anyone other than the PI on a training, practice, resource grant

VCU COI policy

The **VCU COI policy and process** applies to ‘investigators’ on all research, *including*:

- PHS (NIH) funded research
- NIH and other funded research for which VCU is sub-recipient
- sub-recipients from VCU
- research funded by a non-NIH federal entity
- research funded by industry/business
- research funded by any non-profit entity
- research that is not funded at all

PI designates 'COI investigator' on IAF

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PI: _____ Title: _____ Sponsor: _____

-Is this project being conducted through a Center or Institute? Yes: ☐ No: ☐

If "YES", please indicate the Center or Institute:

(The list of Centers and Institutes is available at www.research.vcu.edu/vpr/institutes.htm)

-The proposed project will use the services of the following Service Areas or Core Facility*(attach a copy of approved pricing sheet from each area):

☐ Respiratory Care ☐ Radiology ☐ CCTR ☐ MCV Physicians ☐ Pathology

☐ In-Patient Beds ☐ Nursing Support ☐ Pulmonary/Bronchoscopy ☐ Investigational Pharmacy ☐ CRSO

☐ Health Information/Computing ☐ Survey Evaluation Research Lab ☐ Biostatistics ☐ Other: _____

☐ Core: ☐

* Core facility listing can be found at www.research.vcu.edu/vpr/core_laboratory.htm

PERCENT EFFORT AND PERCENT RESPONSIBILITY ON PROJECT

Key Personnel, Faculty, and “COI Investigator” Designations:

[illegible]

Virginia Commonwealth University Subrecipient Commitment Form

SECTION B - Certifications and Assurances

1. Human Subjects ☐ Yes ☐ No IRB Approval data will be required at just-in-time
2. Animal Subjects ☐ Yes ☐ No IACUC Approval data will be required at just-in-time
3. Conflict of Interest (applicable to NIH, NSF, or other sponsors that have adopted the federal financial disclosure requirements)

- ☐ Not applicable because this project is not being funded by NIH, NSF, or other sponsor that has adopted the federal financial disclosure requirements
- ☐ Subrecipient Organization/Institution certifies that it has an active and enforced conflict of interest policy that is consistent with the provision of 42 CFR Part 50, Subpart F "Responsibility of Applicants for Promoting Objectivity in Research." Subrecipient ☐ is ☐ is not registered on the FDP Institutional Clearinghouse. Subrecipient also certifies that, to the best of Institution's knowledge, (1) all financial disclosures have been made related to the activities that may be funded by or through a resulting agreement, and required by its conflict of interest policy; (2) all identified conflicts of interest have or will have been satisfactorily managed, reduced or eliminated in accordance with subrecipient's conflict of interest policy prior to the expenditures of any funds under any resultant agreement; and (3) all identified conflicts and resultant management plans will be reported to VCU's Office of Sponsored Programs to enable compliance with federal reporting requirements.
- ☐ Subrecipient does not have an active and/or enforced conflict of interest policy and is opting to create and implement its own policy. A sample model policy and report form is located online at http://sites.nationalacademies.org/PGA/fdp/PGA_061001. Signature by the Authorized Official below indicates policy is in place and reporting has occurred as required.
- ☐ Subrecipient does not have an active and/or enforced conflict of interest policy and agrees to abide by Virginia Commonwealth University's policy, Conflict of Interests in Research, located online at <http://www.assurance.vcu.edu/Policy%20Library/Researcher%20Conflict%20of%20Interests%20Policy.pdf>.
- ☐ Complete Attachment 1 if following VCU's policy.

Attachment 1

VCU Activities and Interests Reporting for Subrecipients

VCU's Policy entitled "Conflicts of Interest in Research" will be incorporated into the subrecipient agreement at the time of award. Please review the Policy at <http://www.assurance.vcu.edu/Policy%20Library/Researcher%20Conflict%20of%20Interests%20Policy.pdf>.

I certify that I, and all COI Investigators identified above, have read and understand VCU's Conflict of Interests in Research Policy, will make all required reports, and prior to expenditure of any awarded funds, if applicable, shall have reached an agreement with VCU for conditions or restrictions to reduce, manage, or eliminate any conflicts of interest under the policy.

Subrecipient PI Signature _____ Date _____

Indicate non-VCU collaborators and 'COI Investigators' in RAMS-IRB_(and IACUC)

http://orwirbstage.uc.adp.vcu.edu/irbstage/Resource

File Edit View Favorites Tools Help

Convert Select

Google Search Share More >>

VCU Virginia Commonwealth ... Suggested Sites Gmail - Inbox (2,319) - mo... Gmail - Sent Mail - monik... vcu Virginia Commonwe

VCU Office of Research
IRB STAGING

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Personnel

- * Indicate all VCU/VCUHS personnel that will be engaged in this study:**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other
Update PI TestingB	Co/Sub-Investigator		Study Design Participant Recruitment	
- Identify all non-VCU personnel who will be engaged in this study AND who DO NOT have IRB approval for this study for**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other
There are no items to display.				
- 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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Add SF_IRB_PersonnelAndRoles_Personnel_NonVCU - Internet Explorer, optimized for Bing and MSN

http://orwirbstage.uc.adp.vcu.edu/irbstage/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=18&form=0

Personnel - Non-VCU

- * Name:**
- * Name of Non VCU Institution:**
- Affiliation:**
☐ Non-VCU Affiliate / No Authorization Agreement needed
☒ Non-VCU Affiliate / Authorization Agreement needed
☐ Independent Investigator / No Independent Investigator Agreement needed
☐ Independent Investigator / Individual Investigator Agreement needed
[Clear](#)
- * Is this individual a 'COI Investigator'?**
☒ Yes
☐ No
[Clear](#)
- * Indicate whose COI policy this individual will follow:**
☐ VCU COI Policy
☐ Non-VCU Affiliate's Institutional Policy
[Clear](#)
- * Roles:**
☐ Principal Investigator

Subrecipients & Non-VCU Collaborators

PROTOCOLS - ORSP

‘COI investigator’ status of non-VCU affiliates 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 collaborating institution with responsibilities comparable to VCU PI is likely a ‘COI investigator.’

PROPOSALS - OSP

At a minimum, PIs at subaward institutions are ‘COI investigators.’ Prior to submission of a PHS-sponsored proposal (or a sponsor who is adherent with PHS Final Rule) the subrecipient completes the Subrecipient Commitment Form.

- See form for subrecipient compliance with VCU COI Policy.
http://www.research.vcu.edu/forms/subrecipient_commit_form.pdf

Reporting Financial Interests

‘Investigators’ report Financial Interests, regardless of research funding, in the AIRS.

Each Investigator **reports requested Financial Interests held by himself or herself, or any member of his or her immediate family** (spouse and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent).

'Investigator' reporting in the AIRS

Initial/annual – Report for '*now*' and last 12 months:

- Financial Interests (FI) for self and immediate family
- Research relatedness, if any, to all proposed or ongoing research
- Annually affirm/update accuracy of reported FIs for '*now*' and last 12 months.

Update – Report:

- FI within 30 days of discovery/acquisition of a new entity OR if same entity but new interests are >\$5000 in aggregate.
- Travel update ONLY if new entity is paying
- updated research-relatedness, if applicable
- May need to update research relatedness for new proposal/protocol based on existing FIs

Nothing to update? No relatedness? If entered/updated in last 12 months, no need to re-enter AIRS for specific proposal/protocol submission unless there's a change!

Questions?

For more information:

- VCU COI website – Policy, guidance, etc.:
<http://www.research.vcu.edu/coi/index.htm>
- See VCUERA for AIRS resources – videos and guidance:
<https://www.vcu.edu/vcuera/airs.htm>
- eRAHELP@vcu.edu – for system questions
- AIRS@vcu.edu – for content questions
- AIRS access: <http://airs.research.vcu.edu/>