

VCU Research FCOI Management Matrix

Possible COI management plan scenarios (subject to individual circumstances)

Directions: Column (1) lists types of competing or conflicting financial interests an ‘investigator’ may have in an entity related to, or could appear to be related to, the research to be conducted under the proposed project. An ‘Investigator’ is an individual who has responsibility for the design, conduct, or reporting of research, **regardless of title or role**. If human subjects research, Column (2) lists management options depending on circumstances. Column (3) lists management options for non-human subjects research, depending on circumstances of conflicting interests.

Note: The Matrix addresses scenarios in descending order of occurrence among VCU investigators. Using the Matrix as a guide, the COI Committee makes COI determinations on a case by case basis. The IRB/IACUC may require additional management that pertains to subject protections and welfare.

Advance discussion about COI management is encouraged. Contact the COI Committee Chair or airs.vcu.edu.

***Baseline Management (applies to all managed research)** - Disclosure in manuscripts/professional communication and to students, trainees and depending on type of research, co- or sub-investigators.

	1.	2.	3.
	Type of financial interest with entity sponsoring research or providing products for research (no reporting threshold)	Human Subjects Research – management components for conflicted investigator <u>in addition to baseline management</u>	Non-human subjects – management components for conflicted investigator <u>in addition to baseline management</u>
A	Consulting or speaking relationship with company sponsoring the research (or providing ‘in-kind’ sponsorship, eg. study drug or device) OR Scientific advisory board membership for the sponsoring company	Baseline management* for Financial Conflict of Interest (FCOI) PLUS <i>recommend</i> disclosure in informed consent form (ICF) if = or > \$5,000 in aggregate/year. Depending on level of financial interests, role of conflicted investigator and the type of research, conflicts of interest may require additional management, significant curtailment of investigator activity or may not be amenable to management Financial interests < \$5,000 may be designated as a <u>Competing Financial Interest (CFI)</u> at the discretion of the COI Committee Chair, depending on the type of research and the conflicted investigator’s role in the research. Consider components of baseline management*; possible ICF disclosure. CFI is subject to internal management and is not reportable to funding agencies.	Baseline management* for compensation of = or > \$5,000 Additional management is considered if: a) any ‘investigator,’ especially PI, is promoting company product used in research, b) compensation is substantially > \$5,000

B	<p>Equity interest, that is directly managed by the individual, in a public company sponsoring the research (excluding interests in mutual funds)</p>	<p>If PI, 1) transfer to another PI, or 2) divestiture to maintain investment < \$ 5,000 for duration of study and other management actions, including ICF disclosure.</p> <p>If not PI, divest to < \$10,000 or remove from study. Baseline management* for equity interest < \$10,000 and not PI.</p> <p><i>Recommend</i> disclosure in informed consent form (ICF) for divested PI and all other investigators holding = or > \$5,000 investment.</p> <p>-----</p> <p>Note that equity interest >3% value or >\$5,000 annual (real or anticipated) income, or significant investment levels, may pose a state prohibited contract requiring recommendation of an exception (C.8). An exception and management may not be recommended depending on the case circumstances. See Virginia Code 2.2-3106.</p>	<p>If PI, 1) transfer to another non-conflicted PI, or 2) divestiture to maintain investment at < \$ 10,000 for duration of study.</p> <p>Baseline management* if <\$10,000</p> <p>-----</p> <p>Same state laws issues as Column 2.</p>
C	<p>Direct ownership or equity interest in the non-public company sponsoring the research at VCU (i.e. founding equity, valued equity, options) eg., a start-up company with an SBIR or STTR award</p> <p>See 2.2-3106.</p> <p>Prohibited contracts by officers and employees of state government .</p> <p>Exception permitted at C.8.</p> <p>Note: No exception at C.8 generally allowed if the award to VCU is to be subcontracted to the company.</p>	<p>Baseline management*</p> <p>PLUS</p> <p>notification to co/sub-investigators</p> <p>PLUS</p> <p>Highly recommended disclosure in ICF</p> <p>PLUS</p> <p>Depending on type of research: rebuttable presumption against serving as project PI or co/sub-investigator or supervising designated PI; recommended disclosure language in ICF.</p> <p>If rebutted, CONSIDER:</p> <ul style="list-style-type: none"> - No recruiting/enrolling role; No access to identifiable data; required disclosure in ICF; possibility of external IRB review.. - COI management oversight either inside- or outside-VCU; 'safe person' for communications with peers/students and research subjects <p>PLUS</p> <p>Satisfy C.8 conditions if = or >\$5K or 3% equity to recommend and approve exception from state prohibition:</p> <ul style="list-style-type: none"> - The personal interest is reported prior to contract execution - Conflicted individual files a Statement of Economic Interests initially and annually thereafter - Conflicted individual separates self from financial aspects of the contract with VCU <p>This scenario may also involve an institutional conflict of interest which may be subject to disclosure of institutional interests.</p> <p>Depending on scenario, significant financial interests may not be amenable to management</p>	<p>Baseline management*</p> <p>PLUS</p> <p>notification to co/sub-investigators</p> <p>PLUS</p> <p>Rebuttable presumption against serving as project PI or co/sub-investigator or supervising designated PI.</p> <p>If rebutted, CONSIDER: COI management oversight; 'safe person' for communications with peers/students.</p> <p>PLUS</p> <p>Satisfy C.8 exception conditions from Column 2</p>

D	Ownership or equity interest in sponsoring company relinquished at time of research submission	Baseline management* if interests = or > \$5,000 equity or 3% value in aggregate/year for 12 months after last date of holding. Additional actions if interest was a large amount.	Baseline management* if interests > \$10,000 equity or 3% value in aggregate/year for 12 months after last date of holding.
E	Receipt of royalties from VCU IP Foundation, for technology used in research	Receipt of royalties from VCU Intellectual Property Foundation (IPF) may be considered a Competing Financial Interest (CFI). CFI is subject to internal management and is not reportable to funding agencies. Baseline management* for receipt of royalties from VCU. Additional management may be indicated depending on royalty stream and whether the royalties' recipient is PI. Note that this scenario, depending on the royalty stream, may also involve an institutional conflict of interest subject to baseline management. <i>Recommend</i> disclosure in ICF if amount = or > \$5,000 (amount is not given in ICF).	Consider: Baseline management* for royalties from VCU IPF = or > \$10,000 if recipient is PI.
F	Receipt of royalties outside of VCU IP Foundation, for product used in research (includes direct payment to investigator from company or non-VCU IP Foundation)	Baseline management* for royalties = or < \$5,000. PLUS Notification to co/sub-investigators/students/trainees PLUS Required disclosure in ICF for = or > \$5,000. PLUS Rebuttable presumption against serving as project PI or co/sub-investigator or supervising designated PI if royalties = or > \$5,000. If rebutted - CONSIDER one of more management aspects: - No recruiting/enrolling; - No access to identifiable data; - COI management oversight; - 'Safe person' for communications with peers/students and research subjects. -	Baseline management* for royalties > \$5,000. PLUS Notification to co/sub-investigators/students/trainees PLUS Rebuttable presumption against being PI or co/sub-investigator if = or > \$10,000 If rebutted: Consider one or more: - Publication/abstract oversight for = or > \$10,000; - May require outside-VCU oversight; - May not supervise investigator designated PI
G	Individual or department recipient of sponsor grant or gift for training students, residents, fellows, post-docs	Note: To mitigate COI, all industry-sponsored training grants should be submitted through OSP via non-conflicted PI. Contact AIRS@vcu.edu for guidance. Baseline management* if PI with = or > \$5,000 interest in company. Additional considerations if there are grant/gift stipulations.	Baseline management* if = or > \$5,000. Additional considerations if there are stipulations.

H	Ownership interest or other significant financial interest in a company that is not sponsoring the research, but has a specific interest in the research findings/IP or is a direct competitor with the sponsor.	<p>Baseline management*</p> <p>PLUS</p> <p>Depending on the research:</p> <ul style="list-style-type: none"> - Baseline management extended to co/sub-investigators - Recruitment consideration and other restrictions may apply - Recommend: disclosure in ICF 	Baseline management*
I	Officer or Director for a company or organization sponsoring the research – paid or unpaid	<p>Expectation to recuse self from decision making about research funding to VCU.</p> <p>If paid position: Baseline management* for payment = or < \$5,000. If greater,</p> <p>PLUS Notification to co/sub-investigators</p> <p>PLUS Recommended disclosure in ICF for = or > \$5,000.</p> <p>PLUS Rebuttable presumption against serving as project PI or co/sub-investigator or supervising designated PI if payment = or > \$5,000.</p> <p>If unpaid position: Baseline management</p> <p>PLUS Recommended disclosure in ICF</p> <p>May be subject to C.8 exception under a state prohibited contract. See Virginia Code 2.2-3106.</p>	<p>Expectation to recuse self from decision making about research funding to VCU.</p> <p>If paid position: Baseline management* for payment = or < \$5,000. If greater,</p> <p>PLUS Notification to co/sub-investigators</p> <p>If unpaid position: Baseline management</p>