

# FAQ: FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

## Frequently asked questions on financial conflicts of interest in research and their management

### Definitions and General Questions

*What is a financial conflict of interest in research?*

If a researcher has a personal financial interest that may bias or appear to bias his research, he could have a research related financial conflict of interest (FINANCIAL COI). Virginia law and federal research rules define and regulate these conflicts.

*How do I tell if I may have a research related FINANCIAL COI?*

You may have a research related FINANCIAL COI if you have a triggering financial interest in either:

- a company that sponsors your research, or
- a company, other than the sponsor, that may be affected financially by your research. Example: if you own stock in or receive consulting income from a company whose product would benefit if the results of your research are positive, you may have a FINANCIAL COI, even if the company is not the research sponsor. Or you may own stock in a competitor, so that negative results from your research could benefit that competing company and your financial interest.

*What is a conflict-triggering financial interest?*

If you, your spouse, your financially dependent children, and any other persons who live in your household and are dependents (or of whom you are a dependent)\* have any of the following financial interests, that interest may trigger a FINANCIAL COI:

- more than 3% of the equity of the company (in stock, stock options, partnership interests or as a sole proprietor), or equity that exceeds \$10,000 in value (but not ownership of equity through mutual funds)
- annual income from the company that exceeds, or is expected to exceed, \$10,000 (e.g, consulting fees, honoraria, salary and benefits, dividends, or royalty income from licensure of patents or copyrights)

\*Note: to determine if you have a triggering ownership or income interest, your interests and those of your spouse and dependent children should be aggregated.

*I may have a FINANCIAL COI. Are all research conflicts of interests prohibited?*

Not necessarily. If your financial interest triggers a research FINANCIAL COI under Virginia law, it may be possible for the University to approve an exemption for the conflict. And under the federal research conflict rules, it may be possible to manage or reduce the FINANCIAL COI instead of prohibiting it.

*What do I need to do about my possible research FINANCIAL COI?*

Contact the administrator for your school (See contacts listed below).

Your administrator will help you to identify and disclose the details of your FINANCIAL COI, so that it can be reviewed by the UVA Research Conflict of Interests Committee. The Committee will recommend whether your FINANCIAL COI can be exempted under Virginia law, and whether and how it can be managed or reduced to satisfy the federal research rules.

*Besides my financial interests, what other information will the Research Conflicts of Interest Committee need from me?*

- Whether you or your family members are on the board of directors of the company.
- Whether the company also makes gifts to the University, supports fellowships, or sponsors educational events
- Whether the company also sells products or services to the University
- If your research involves human subjects, **any** amount of ownership or income interest you or your family members have in the company.

The disclosure form that you will need to fill out can be found at:

<http://www.virginia.edu/vprgs/coi/index.html>.

*Do these FAQs cover all of the laws and University policies about FINANCIAL COIs?*

No. These FAQs are aimed at helping you understand the research FINANCIAL COI laws and policies but are not a substitute for them, or for consulting with University administrators who can help you apply the laws and policies to your particular case. Also, some schools in the University may have their own policies. And conflicts of interests can be created by circumstances outside of research—for instance, receiving consulting fees or stock from a company that sells products to the University. See the laws and policies linked below:

State laws on financial conflicts and disclosure requirements may be found in Section 2.2-3100 et seq. of the Code of Virginia. See <http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC0202000003100000000000>

Federal Requirements are included in 42 CFR Part 50, Subpart F, and 45 CFR Part 94. For more detailed information and links to these regulations and federal policies on financial conflicts of interest related to human subject research, consult

<http://grants.nih.gov/grants/policy/coi/index.htm>

University of Virginia policies may be found at:

<http://www.virginia.edu/vprgs/objectivity.html> and

<http://www.virginia.edu/finance/polproc/pol/xva1.html>

### **SBIRs, STTRs, and financial COI**

*What are the different requirements of SBIRs and STTRs? How does each of these funding mechanisms relate to financial COIs?*

Background/concerns. Because these funding mechanisms often involve investigator-owned companies, we offer this concise description of these programs. Eleven federal agencies fund SBIRs (Small Business Innovation Research Grants); five (Energy, DHHS, Defense, NASA, and NSF also fund STTRs (Small Business Technology Transfer Grants). The differences between these award mechanisms are outlined below. Additional information on these programs can be found at the [Small Business Administration](#).

<b>Characteristic</b>	<b>SBIR</b>	<b>STTR</b>
Goal	R&D efforts during a company's start-up phase	Technology transfer, followed by commercialization
PI's employer	Primarily employed by small business	Can be employed by university/associated with small business
University partner required?	No	Yes
Pct. of work performed at small business	Phase I: at least 67% Phase II: at least 50%	Phase I: ≥40% Phase II: ≥40%
Pct. Of work performed at university partner	Phase I: ≤33% Phase II: ≤50%	Phase I: ≥30% Phase II: ≥30%
Written agreement on IP rights	No	Yes
Phase I maximum	\$100K/6 months	\$100K/12 months
Phase II maximum	\$750K/24 months	\$500K/24 months

STTRs have the added potential for the same individual being the overall PI and the PI of the University subcontract, though each type of award might involve a faculty company. For either funding mechanism, financial COI comes into play when a University employee has a financial interest or receives income from the company wishing to collaborate with UVA. See additional information in the next section that is pertinent to SBIRs and STTRs.

### **Contracts between faculty companies and UVA**

*How do contracts from my own company to UVA differ from other UVA research awards, and how can I minimize any effects of my financial COI?*

Background/concerns. Several UVA faculty have started their own companies or are partial owners in colleagues' ventures: these both are covered in this section. The following areas are of importance with respect to University-company contracts:

- The COI Committee must decide whether the proposed work at the University is consistent with the institutional mission, or whether it would better be performed by the company itself or contracted to a third party.
- Because the investigator is proposing research to be funded by his/her company, it is important to ensure that all costs of the scope of work be compensated: the University cannot subsidize such work (see the "Financial" section below).
- The [Virginia COI Act](#) prohibits state employees from negotiating contracts with UVA on behalf of their own companies when they have an ownership interest above 3% (cf. §2.2-3110.5). When state employees have an interest in a company only due to income in excess of \$10,000, they are prohibited from

participating in the procurement or letting of such a contract on behalf of the company (cf. §2.2-3110.4). However, it may be possible to obtain a waiver of COI from the President under the research conflict of interests exemption (per §2.2-3016.8).

Recommendations. When proposing a contract with a faculty company, you must make a detailed and convincing case that the work scope is appropriate to the University's mission and that UVA will recover all of the costs of the work to be performed here. Furthermore, if you have a small start-up company, hire an attorney to handle contract negotiation and financial management of the subcontract. Larger companies usually have available an individual who is tasked with contract negotiation.

*If I have a financial interest in the sponsoring company, may I oversee the contract with UVA?*

Background/concerns. Even if you are not the UVA Principal Investigator, your financial COI might cause you to influence the PI's direction of the project or his/her interpretation of its results. See below under "University reporting lines" if the PI reports to you administratively or if you are responsible for decisions such as promotion, tenure, or annual salary.

Recommendations. If you have a role within the company that requires you to oversee the UVA contract (e.g., Chief Scientific Officer), it is appropriate to discuss with the UVA PI the general direction and results of his/her research, most appropriately by means of contractually required technical reports. Do not exercise any efforts beyond those allowed by the contract: the UVA PI should have the freedom to conduct, interpret and report and publish the results of his/her research within the agreed-upon work scope.

*How can I minimize my financial COI when my company subcontracts with UVA?*

Background/concerns. Contracts to other entities generally occur when the University has received funding for a project that it cannot complete without external collaboration. As is the case with contracts in the opposite direction, subcontract proposal and contract negotiation are important areas of concern. If you are the UVA PI overseeing the subcontract, your financial COI might affect University oversight.

Recommendations. Please consider the following:

- Provide a strong rationale for why your company (rather than UVA or any other outside entity) should perform the proposed work scope.
- When preparing the subcontract budget, take great care to ensure that the level of funding requested is appropriate for the work scope. Expect that this aspect of the proposal will be reviewed carefully by the COI Committee.
- As above, recuse yourself from any involvement in the negotiation of the subcontract.
- Recommend that independent individuals within the University perform post-award oversight of the subcontract, including approval of invoices and technical progress. Such oversight might include examination of technical progress reports and whether company expenditures are appropriate to the original budget and work scope.

*What other issues are of importance in the appropriate conduct of research projects that involve both UVA and a faculty company?*

Recommendations. The following also are of importance in minimizing the effects of a financial COI:

- Reporting of new inventions (see "Reporting intellectual property" below).

- Separation of company and University scopes of work. On SBIRs, STTRs, and similarly structured projects (i.e., each entity performs a portion of a broader, unified scope of work), there should be no overlap between the two subprojects. Overlap could affect financial, intellectual property, and other issues. The COI Committee will expect to see an explicit separation of company and UVA subprojects.

## Financial

*What are my financial responsibilities to the University, and how can I ensure that my COI does not suggest any potential impropriety?*

Background/concerns. The University cannot subsidize the research of any private entity. Specifically, such projects cannot utilize uncompensated employee effort, or use of facilities, or funds.

Recommendations. The investigator and his/her administrators must create a firewall between the COI project and other funding sources. Consider the following:

- Maintain a detailed effort log for all employees in your research group, documenting that the level of effort expended on your COI project does not exceed the reimbursed levels in your contract.
- “Contributed” faculty time for your COI project should be approved *a priori* by your Chair and, if appropriate, Dean.
- Recommend an independent review of the proposed budget for your COI project, to ensure that you have not underestimated the cost of performing the work scope.
- Recommend an independent review of financial expenditures, to establish that no external funds have been used in the conduct of your COI project.

## Use of University facilities

*Can my company have access to University facilities or resources?*

Background/concerns. Your company can use University facilities and resources only if the University agrees to enter into a formal contract with your company that covers the entire cost of your company’s use. Establishment of the true cost of such use is critical. University policies restrict faculty and staff from using University employees, e-mail systems, servers, desktops, fax machines, etc., for private use (including use on behalf of one’s company).

Recommendations. Before allowing your company to use any UVA facilities, you must establish a UVA-approved rate schedule for their use and methods for tracking use and for invoicing. You should not be in charge of or oversee the facility to be used by your company; nor should you participate in developing the rate schedule. Contact the Office of Financial Analysis for further information on this process. All other use of UVA facilities and resources is prohibited.

## University reporting lines

*I have started a company that I co-own with my colleagues/staff/trainees. What potential problems might this add to my COI and how can I overcome them?*

Background/concerns. We have combined co-ownership and receipt of payments from the company here. UVA policy requires that your decisions as a supervisor not be influenced by potential financial gain. Examples of such situations might include

disputes within the company that influence your decisions as a UVA supervisor. Furthermore, the inclusion of your direct reports as co-owners in your company might suggest overt or inadvertent coercion.

Recommendations. Whenever possible, avoid having your direct reports invest or receive money from your company, and vice-versa. (This would also apply to investing in or receiving money from your supervisor's company.) When these cannot be avoided, attempt to remove supervisory responsibility from the financial COI by proposing the appointment of a third party to oversee the individuals being supervised or to act as their ombudsman.

### **Reporting intellectual property**

*What are the pitfalls and potential solutions with respect to new inventions created during a project where I have a financial COI?*

Background/concerns. As a UVA employee, you are bound by its [Patent Policy](#), which states that all inventions must first be disclosed and assigned to the UVA Patent Foundation rather than to other entities. The Foundation, not the inventors, determines which companies will license institutional intellectual property. Furthermore, disclosure to outside entities (e.g., your company) prior to filing a patent application may limit foreign patent rights.

Recommendations. This is yet another instance where the faculty member must create and maintain a firewall. When you disclose to the COI Committee a proposed project where you have a financial COI, it would be helpful to state that all resulting inventions from a project will be the property of the University and be disclosed only to the Patent Foundation – and adhere to this practice.

### **Ensuring data integrity**

*If I have a financial conflict, how can I best maintain the integrity of my data and of resulting reports and publications?*

Background/concerns. A financial conflict might cause certain investigators to veer from responsible conduct of research (e.g., re-running experiments with unexpected results, not reporting all of the data that were generated, over-interpreting data to support one's hypothesis, etc.). The broader topic of research misconduct is covered by [UVA Policy RES-004](#).

Recommendations. Consider proposing to the COI Committee the appointment of a knowledgeable faculty colleague(s) (who does not report to you) to review your data, analysis, and resulting reports and manuscripts.

### **Trainees**

*What measures must I take to protect trainees who might participate on research projects where I have a COI?*

Background/concerns. Trainees include students, postdocs, research fellows, and residents. They depend on faculty advisors for financial support, research guidance, and advice on career development. It is possible that a faculty member might assign trainees among projects based on his/her financial COI rather than their career development.

Recommendations. If possible, do not include trainees on projects where you have a financial COI. For instance, if you have a federal award and a subcontract from your own company, consider having the trainee work on the federal award. If this is either impossible or if a trainee's career development would be enhanced on the award with the COI, strongly consider proposing to the COI Committee a third-party to oversee the

trainee's assignment among projects and progress toward his/her degree or other successful completion of training.

### **Human subjects research**

*As a clinical investigator, am I precluded from performing research where I have a financial conflict of interest?*

Background/concerns. The most common scenario is testing a drug, device, or biologic for a company from which you receive income or in which you have ownership. Financial gain might also result from testing a product in which you have intellectual property rights (see "Intellectual property rights and clinical research" below). In such research, the safety of research subjects might be subordinated to the financial interests of the investigator. Another important factor is that time to completion of a trial can represent a large financial incentive, as it relates to subsequent sales and market share for that product. The Conflict of Interest Committee and the Institutional Review Board make the rebuttable presumption that individuals with COIs cannot be involved in human subjects research.

Recommendations. Minimizing the potential influence of an investigator with a financial COI on recruitment, study procedures, data collection and analysis, and reporting/publication can help obtain committee approval. The simplest solution is to remove the conflict by finding another qualified UVA investigator, who does not report to you, who will conduct the clinical study. In such circumstances, you should state that you will not participate in the conduct or reporting of the research. You also can remove your COI by selling stock or canceling any financial relationships with the company before initiating the study. (This might be coupled with a promise not to purchase stock or enter into any additional financial agreements with the company until a reasonable period after the completion and publication of the study.) If neither of these is possible, consider strongly the following factors when requesting a waiver of COI:

- Investigators with COIs are less likely to manipulate the results of multi-site studies than single-site studies, since they will recruit a smaller proportion of subjects; also, the resulting manuscripts tend to be written by committee.
- Having non-conflicted individuals who do not report to the conflicted investigator, recruit and consent subjects is more appropriate than having an individual with a COI perform that responsibility. (Recall the problems of personnel reporting described above.)
- Have a "blinded" surgeon, physician, nurse practitioner perform any study-related procedures.
- Clinical coordinators might collect and enter data directly into a computerized database management system and respond to queries during data cleaning. Deny yourself access to those data until they have been cleaned and the final study database locked.
- Consider having a contract research organization perform data analysis.
- During the conduct of the clinical research study and through its final reports and publications, you should not receive any other honoraria, consulting fees, or other such payments from the sponsor. Payments for finding subjects or attaining specific recruitment goals are prohibited by the University.
- Changes in equity during the study. It is strongly recommended that you and your family not purchase or sell stock in the sponsor of a clinical study that you are performing. Stock transactions based on insider information are prohibited by federal law.

Regardless of the management plan for your COI, the IRB will require that you disclose your financial conflict to potential research subjects in your consent form.

### **Intellectual property rights and clinical research**

*Can I conduct clinical studies of my own inventions (drugs, devices, biologics)?*

Background/concerns. Under the UVA [Patent Policy](#), inventors share in licensing fees and royalties generated by their own inventions. Early stage clinical trials of such inventions may not create immediate financial benefits, but could increase the marketability of such technologies to potential licensees.

Recommendations. Ask another qualified UVA investigator, who does not report to you, to conduct the clinical study. In such cases, it is strongly urged that you avoid all of the following:

- Contact with the IRB concerning approval of the protocol.
- Contact with potential or consented research subjects.
- Involvement in medical procedures associated with the study.
- Data collection, cleaning, analysis, interpretation, or reporting/publication.
- Discussion with the Principal Investigator of interim or final results of the study, prior to their publication.

These proscriptions are independent of your obligation to “cooperate in the patenting and licensing of the invention or discovery” (UVA [Patent Policy](#)).

### **Public disclosure of your COIs**

*What types of public disclosure are appropriate, in light of my COI?*

Background/concerns. Disclosure of financial conflicts is considered the norm within the scientific community, in journal publications, in CME presentations, and in scientific presentations.

Recommendations. Recommend to the COI Committee that you will disclose your financial conflicts in all presentations, reports, and publications resulting from the research. The IRB will require disclosure of COIs during recruitment, in the consent form.

### **Points of Contact for COIs by School**

#### ***School of Architecture***

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