

Frequently Asked Questions

Columbia University Policy on Financial Conflicts of Interest and Research

Overview

1. Why does Columbia have a new Policy on Financial Conflicts of Interest and Research?

Financial conflicts of interest in research have the potential to increase bias in research or create the appearance that research has been biased, regardless of whether or not that is the case. They also can present risk to human subjects participating in research. Columbia's new policy, like its previous policies, helps assure appropriate relationships with commercial entities for the benefit of researchers, the University, and the public, and thus maintain the public trust in the research enterprise.

Until now, Columbia has had several policies governing conflict of interest in research, including general policies and a policy specifically for Columbia University Medical Center. In an effort to harmonize University policies and in light of the increasing emphasis on interdisciplinary and cross-campus collaborations—including by funding agencies—the University is adopting a single policy governing financial conflicts of interest in research across the University. The new policy incorporates many concepts and provisions of the previous policies and procedures. It also aligns Columbia with current best practices in this particularly sensitive area.

2. What is a conflict of interest?

Conflicts of interest can arise from many different circumstances, including personal relationships, the desire for professional status or fame, and other concerns. This Policy does not address all conflicts of interest. Instead, as its title indicates, this Policy concerns financial conflicts of interest in research.

A financial conflict of interest is a situation where an individual's private financial interest might interfere or appear to interfere with his or her professional obligations to Columbia or the conduct of the research. Such situations do *not* necessarily imply wrongdoing or inappropriate activities. However, in a research university setting, they can compromise, or be perceived as compromising, important academic values, research integrity, or the university mission.

3. How can one policy be appropriate for an institution as diverse as Columbia?

While Columbia is a diverse institution, all researchers share a common interest in research integrity. However, recognizing that different research communities may face different issues, the University is establishing a single Financial Conflict of Interest Committee comprised of two sub-committees, one for CUMC and one for the rest of the

University, which will implement the Policy. The sub-committees will coordinate with each other and with other conflict-of-interest processes at the University. Where University-wide issues arise, they will be reviewed by the full Committee. In this way, the University will implement a single policy with flexibility, on a case-by-case basis.

4. Whom does the Policy cover?

Any individual (officer of instruction, officer of research, staff, fellow, student, administrator), regardless of geographic location, who is responsible for the design, conduct or reporting of research under the University's auspices is covered by the Policy.

5. What does the Policy require?

The Policy requires:

- Disclosure of any relevant financial interests to peers and to the public in any publications, reports, presentations.
- Completion of conflict of interest disclosure forms, called Financial Interest Reports, at least annually, for University review. The Reports must include any financial interests that could reasonably appear to be affected by research that is funded through Columbia (externally or internally) or subject to regulatory review by a Columbia regulatory body.

The Policy also requires that potential conflict of interest issues (as set forth in the Policy) be reviewed by the Financial Conflict of Interest Committee ("FCOI Committee"). The FCOI Committee will determine how each case should be handled, based on its own individual facts. After making its determination, the FCOI Committee will notify the investigator of its determination, and the investigator will need to confirm that he or she has complied.

6. What do I need to report?

You must report any Financial Interests (see Question 7) that might reasonably appear to be affected by any of your research that is funded through Columbia (externally or internally), or is subject to regulatory review by a Columbia regulatory body (e.g., the Institutional Review Board). These include but are not limited to any financial interest in an Interested Businesses, i.e., any business that:

- funds your research in whole or in part, whether through a research agreement, gift, or other arrangement;
- supplies drugs, devices or other goods that are the subject of your research, or services or other deliverables in connection with the research, pursuant to a material transfer agreement, a research agreement or otherwise;

- holds an Investigational New Drug application (“IND”) or Investigational Device Exemption (“IDE”) for a technology being investigated in your research;
- owns, licenses or has any other contractual interest in a technology being investigated in your research; or
- acts for or on behalf of another Interested Business, directly or indirectly. Depending on the relationship, this could include some medical education companies and other similar entities.

You also must report any other financial interest that could reasonably appear to be affected by your research. Such interests could include a patent held directly by you or a member of your family, rather than one held by the University. It could also include real property or other property interests held by you or your family.

7. What does “Financial Interest” include?

A “Financial Interest” is any financial interest in an Interested Business or any other financial interest that would reasonably appear to be affected by the Research at issue, held or received by you or your Family.¹ A “Financial Interest” includes:

- salary or other compensation for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stock, stock options or other ownership interests);
- intellectual property rights (e.g., patents or copyrights);
- royalties, license fees, or similar payments from intellectual property rights that are related to the research at issue; and
- directorships, executive roles and other special relationships with a business.

A Financial Interest does *not* include:

- salary or other remuneration from the University other than Royalty Payments;
- income from seminars, lectures or teaching sponsored by nonprofit or public entities;
- income from service on advisory committees or review panels for nonprofit or public entities;
- royalties or other income received from an independent publishing company arising out of books (print or electronic) authored or co-authored by an Individual;

¹ Although Financial Interests typically exist in relation to a Business, this Policy also requires disclosure of financial interests even where no Business is involved if the financial interest could reasonably appear to be affected by the Research. Such financial interests could include, for example, a patent owned personally by the Individual rather than by the University or another entity.

- diversified financial holdings that are not controlled, influenced or managed by the Individual (e.g., mutual funds); and
- financial interests held by your Family but not known to you, except for interests held your spouse or domestic partner or dependent children, which are deemed to be known by you.

Researchers must report their own interests as well as those of their spouse, domestic partner and dependent children, and those of their parents, adult children, grandparents and grandchildren that are known to them.

8. Does the FCOI Committee review all financial interests?

No. The FCOI Committee will review only “Financial Interests” related to your research (see Question 7) that exceed the threshold for “Significant Financial Interests.” However, where the research involves human subjects, the disclosure of any outside financial interest, regardless of its value, is provided to the IRB. See Question 11.

9. What is a Significant Financial Interest?

Significant Financial Interests include the following Financial Interests:

- salary or other income from an Interested Business (see no. 6 above), whether for consulting, lecturing, travel, service on an advisory board or for any other purpose that in the aggregate has in the prior twelve months exceeded \$10,000, or is expected to exceed such amount in the next twelve months;
- for a **publicly held business**, an equity interest that exceeds: (i) \$10,000 in value or (ii) 5% ownership in the business;
- for a **privately held business**, any equity interest, regardless of the amount;
- royalty payments, including those received under a University agreement, that in the aggregate have in the prior twelve months exceeded the amount set by the PHS Threshold, or are expected to exceed such amount in the next twelve months; and
- service as an officer, manager, member of a board of directors, or in any other fiduciary or managerial role, whether or not remunerated.

10. How will the FCOI Committee review my financial interests?

The FCOI Committee will look at each case individually. The Policy provides that it is not ordinarily allowable for an individual who has a Significant Financial Interests in an Interested Business to conduct research involving that Interested Business. However, in some cases, the FCOI Committee may determine that there are countervailing circumstances that justify continued participation by the conflicted

individual in the Research. The policy identifies a number of review factors to assist the Committee in making these determinations.

If countervailing circumstances are present, the FCOI Committee will work with the researcher to develop a management plan to manage the conflict.

Absent countervailing circumstances, the FCOI Committee will direct the researcher to divest from the Significant Financial Interest or withdraw from the research.

11. Are there any special requirements for human subjects research?

Yes. Researchers involved with the design, conduct or reporting of any human subjects research protocol must submit a project-specific disclosure form. All Financial Interests—even those below the Significant Financial Interest threshold—must be disclosed to the Institutional Review Board (“IRB”). And, notwithstanding FCOI Committee resolution, the IRB may impose its own requirements on your research if it involves human subjects. For example, the IRB might require particular language disclosing financial interests in informed consent forms, even if the interests are below the \$10,000 threshold.

12. Why is the threshold for certain Significant Financial Interests set at \$10,000? Does the \$10,000 threshold apply to both government and private funding sources?

The \$10,000 threshold has been adopted by Association of American Universities and the Association of American Medical Colleges and many of our peer institutions. The National Science Foundation and the U.S. Public Health Service (PHS) both mandate a \$10,000 threshold for Significant Financial Interest. In order to promote fairness and avoid multiple standards across disciplines, Columbia has adopted this standard for all research conducted under Columbia’s auspices, regardless of funding source.

13. Is the information I disclose confidential?

Yes. The University recognizes that disclosed information may be sensitive and limits access accordingly. Disclosures are made electronically through Rascal, a restricted research administration database. The completed forms are available to the staff in the Office of Research Compliance and Training, which conducts initial review of the disclosure forms, and, where appropriate, to members of the FCOI Committee, who are obligated to keep the information confidential.

Where a disclosure relates to human subjects research, it also will be shared with the Institutional Review Board. In addition, disclosure forms may be shared with other University officials or committees with conflict of interest responsibilities, who also are obligated to keep the information confidential. Beyond these individuals, disclosure forms will be made available on a “need-to-know” basis only, such as in response to audit inquiries or other special circumstances.

14. I don't know the holdings of my parents or my adult children, let alone my grandparents or grandchildren. Does this mean I have to ask them for their financial information?

No. You need only report financial interests of your parents, adult children, grandparents and grandchildren if you are already aware of those interests. There is no duty to inquire about those interests.

15. What about my spouse's interests, and the interests of my dependent children?

These financial interests must be reported. Because these relationships are so close, you are deemed to know about them even if in actuality you do not. The University recognizes that for some people, this may require additional inquiry.

16. What about mutual funds? Do I need to investigate if the mutual fund in my retirement account holds stock in the company that is funding my research?

No. Financial holdings that are not controlled by you (such as mutual funds) are excluded from the definition of "Financial Interest."

17. I thought the University permitted Officers of Instruction to consult up to one day a week. Doesn't this Policy restrict consulting?

This Policy does not change the University's policy on consulting. The University permits officers of instruction to consult for an average of one day a week, provided that the consulting does not interfere with University obligations and is appropriately approved. See The Faculty Handbook, Outside Interests and Employment (2008 ed., pp. 156). Under the Policy, consulting for an Interested Business (as defined in Question 6 above) for a fee that exceeds \$10,000 per year must be reviewed by the Financial Conflict of Interest Committee.

18. What happens if I don't file a Financial Interest Report or my Report is incomplete?

Reporting outside financial relationships is a responsibility every member of the Columbia University community must view with the utmost seriousness. While full disclosure may sometimes require a review of financial records or other efforts, it is nonetheless critical to the conflict of interest review process. In addition, only full disclosure avoids post hoc revelations that have the potential to lessen public confidence in the objectivity of research, not to mention embarrass researchers who have not fully disclosed.

As is currently the case, without a current annual Financial Interest Report, you will not be permitted to submit proposals for new research funding. Similarly, the

Institutional Review Boards will continue to not grant final approval of human subjects research protocols until any potential conflict issues are resolved. Deliberate non-disclosure is subject to the full extent of University penalties, as set forth in the policy.

19. I have seen a lot of articles about government investigations into conflicts of interest and research. What happens if the government investigates possible conflicts of interest in my research?

The University would initially take the lead in responding to any such investigation. The University supports personnel who are subject to external investigations, provided that the personnel have complied with University policy and were acting within the scope of their employment. Ultimately, however, it is the responsibility of each individual to avoid conflicts of interest with respect to his or her research.

Reporting Process

20. How do I file my Financial Interest Report?

As is currently the case, all reporting is made through Rascal, the University's research administration software system. You will need to log in with your UNI and password. You may access the Rascal Conflict of Interest module here: <https://www.rascal.columbia.edu/coilogin.html>.

21. When must I file disclosures?

Upon hire: Filing an Annual Financial Interest Report should be one of the first tasks you complete upon hire at Columbia.

Every year: Thereafter, you will be automatically prompted by Rascal to file on an annual basis.

Updates: In addition to your yearly filing, you are required to update your annual form in Rascal if (and as soon as) you have a new Significant Financial Interest related to your research. This could occur due to either a change in your or your family's financial interests or in the nature of your research. Some examples include:

- the value of an existing financial interest increases so that it exceeds the PHS Threshold;
- you conduct or plan to conduct new research that relates to an existing financial interest held by you or your family.

If, at any time during the course of the year, you need to update your disclosure, you may log into Rascal and file a new disclosure form.

Human subjects research: For human subjects research, at the time that you submit your protocol to the Institutional Review Board, you will be automatically prompted by Rascal to file a project-specific disclosure form.

22. Can I view disclosures from prior years?

Yes. Once you log into Rascal, you can view all of your disclosures.

23. Is the Financial Interest Report the only conflict-of-interest form I need to complete?

Not necessarily. The Financial Interest Report addresses conflicts of interest and research along with other issues such as administrative conflicts and conflicts of commitment. In addition, for faculty of the College of Physicians and Surgeons (P&S) only, the form contains additional questions related to the P&S Conflict of Interest Policy on Education and Clinical Care.

University faculty with administrative responsibilities may also be required to fill out a separate conflict of interest form regarding their administrative activities.

24. I have a Significant Financial Interest, but the FCOI Committee has determined that I may continue to participate in the research under a management plan. Must I disclose the Significant Financial Interest to my graduate students, research colleagues and collaborators within and outside the University?

Yes. You must disclose this information to the members of the research team, and you must also disclose it in all relevant reports, publications and presentations and as otherwise required (*e.g.*, by an IRB).

25. Should I make this disclosure in writing?

A written disclosure, although not required, provides you with a record of your compliance, and protects you should questions arise about your notification of others about your conflict of interest.