

The Office of Academic Affairs

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Conflict of Interest

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FAQs

FAQs for the P&S COI Policy on Education and Clinical Care

NOTE: These FAQs are subject to changes/additions over time, reflecting more experience with the policy and evolving professional standards. Please see the Annual Announcement to Faculty and Researchers for more information.

GENERAL FAQs

- 1. Why is there a P&S COI Policy on Education and Clinical Care ("P&S COI Policy")?** Since January, 2009, the P&S COI Policy specifically addresses two critical areas particularly relevant to P&S: clinical care and medical education, while reinforcing the general principles set forth in University policies. The policy is updated annually.
- 2. How can I access the policy?** The policy is posted on the website of the P&S Office of Academic Affairs: www.cumc.columbia.edu/faculty/coi/
- 3. How does our policy compare with those of other major academic medical centers?** The P&S policy is congruent with 2008 guidelines from the Association of American Medical Colleges, and is comparable to recently developed policies at other major academic medical centers.
- 4. Does this policy replace other COI policies?** No. This policy adds to the existing University COI policies set forth in the Faculty Handbook. These other University policies address issues including COI in research, self-dealing, and other areas.
- 5. How is the policy being implemented?** This policy is overseen by the Vice Dean of Academic Affairs at P&S, Dr. Anne Taylor. Additional oversight comes from the P&S COI Committee on Education and Clinical Care. Oversight is coordinated with the existing process for oversight of research COI under the CU Executive VP for Research and the CUMC COI Committee on Research (chaired by Dr. Henry Spohnitz). Close coordination exists amongst the administrative leadership.
- 6. What is the role of Department chairs and other supervisors in oversight of the P&S COI Policy?** Chairs and other supervisors are charged with maintaining institutional standards within their respective departments.
- 7. Does this policy pertain to Faculty and Researchers at the other CUMC schools – i.e. Public Health, Dental, Nursing?** No. Each CUMC school has its own policy. Questions on the COI disclosure form are designed to be consistent with all of the CUMC policies on COI in Education and Clinical Care. In contrast, the University policies on COI in research and other areas apply to all of CUMC.
- 8. Under the P&S COI Policy, who needs to file an annual COI disclosure?** All full- and part- time P&S Officers of Instruction ("Faculty") or Officers of Research ("Researchers") must adhere to the policy and complete the annual disclosure.
- 9. Compliance:** Disclosure is required for renewal of annual faculty appointment. Failure to comply with mandatory policies will prompt formal review by the CUMC COI Review Committee on Education and Clinical Care, with recommendations to the Dean, and may

lead to sanctions up to and including non-renewal of appointment. plete the annual disclosure.

10. **Is annual disclosure the only mandatory aspect of the P&S policy?** No. External activities cannot be allowed to influence teaching, research or patient care activities. Some commercially supported activities are not permitted. Officers must comply with management plans recommended by the CUMC COI Review Committee on Education and Clinical Care. (See policy: www.cumc.columbia.edu/faculty/COI)

11. **How do I file my annual COI disclosure form?** The disclosure form is filed in RASCAL (www.rascal.columbia.edu) under the module, "Conflict of Interest."

12. **What if questions on the disclosure form do not pertain to me?** You must answer all of the primary questions (yes or no). Several of the questions have sub-parts; if you answer "No" to the primary question, no sub-part will arise. For each "yes" answer, you must answer each sub-part and provide additional information, as prompted on the form. Definitions of the terms used in the form are posted on the RASCAL COI module.

13. **If I disclosed a Significant Financial Interest in response to one question, and the same interest also is relevant to another question in another section, do I need to disclose the interest again?** You need to answer "Yes" to all relevant questions within each section of the form. **Even if you have already disclosed the information in the Research section, outside financial interests must again be disclosed in the C/E section.**

14. **Do I need to disclose information pertaining only to on-campus business activities?** No. Disclosure is required for all professional business activities, whether they occur on-campus or elsewhere.

15. **Do I need to disclose salary or other payments I receive from Columbia-affiliated entities for clinical services performed on behalf of CUMC schools?** No, you do not need to disclose salary or other payments received for clinical services on behalf of Columbia.

16. **What if I am primarily employed by an entity other than Columbia or one of its affiliated institutions or associates?** You will be asked if you are employed by another entity and to name it.

17. **What do I need to disclose if I or my spouse has a non-salaried appointment at Columbia?** All P&S Faculty and Researchers with a Columbia appointment are required to file an annual COI disclosure, including those with a non-salaried Columbia appointment. However, a salaried P&S Faculty or Researcher with a non-salaried spouse may answer "no" to the question about whether their spouse is employed by Columbia.

18. **What if I have already recently filed an annual disclosure form in RASCAL?** Beginning in 2009, P&S Policy requires that all P&S Faculty and Researchers file an annual COI disclosure via RASCAL, regardless of when/if a disclosure form has been previously filed.

19. **Are there 2 annual COI disclosures, one each for research and another for education/ clinical care?** No. Most Faculty and Researchers from all of the four CUMC schools (P&S, Dental, Nursing, Public Health) will only need to submit one annual COI form for CU/CUMC. For clinical Faculty, NY-P (or other hospitals) may also require filing a hospital-specific COI disclosure form. Individuals conducting human subjects research will continue to be required to file a protocol-specific disclosure in addition to the annual disclosure.

20. **What will happen with my disclosed information?** Information disclosed in connection with the P&S Policy will be reviewed by the P&S Office of Academic Affairs and by the CUMC COI Review Committee on Education and Clinical Care for appropriate action. Correspondence and Committee decisions will be archived in RASCAL. Information pertaining to other conflict of interest policies will be handled in accordance with existing COI procedures.

The CUMC Review Committee on COI in Education and Clinical Care reviews disclosed information and relevant correspondence. Faculty or Researcher responses to this Committee are deemed acceptable by fulfilling these criteria:

- Responses to questions posed by the Committee are clear, complete and timely;
- There is clear separation between the disclosed commercial interests and his/her professional duties in education and clinical care.
- Compliance with recommendations by the CUMC COI Review Committee on Education and Clinical Care is demonstrated.

Starting in 2012, some information disclosed on the annual COI form regarding education and clinical care will be available on a publicly accessible CUMC website. Faculty and Researchers will be able to preview the information and make corrections to their form prior to submission. This decision was based upon the fact that pharmaceutical and devices companies are making such information public, that legislation may, in the near future, require public disclosure of financial relationships and the increasing prevalence of this practice by peer institutions.

21. **Is my disclosure confidential?** As of 2012, some disclosed information may be made publicly available through a publically accessible website. This decision was based upon the fact that pharmaceutical and devices companies are making such information public, that legislation may, in the near future, require public disclosure of financial relationships and the increasing prevalence of this practice by peer institutions.

22. **Do I need to disclose relevant commercial income from my spouse?** Yes, that aspect of the policy has not changed. Commercial income from oneself or one's spouse will be reviewed for possible conflict for that Faculty' or Researcher's educational and clinical duties. The exact amount of spousal commercial income over \$50,000 annually does not need to be disclosed.

23. **What if I don't submit the annual COI disclosure form?** As of January 1, 2009, all P&S Faculty and Researchers have been required to submit an annual P&S disclosure form. Non-submission is a breach of academic duties and may result in non-renewal of academic appointment. Also, a current annual disclosure form in RASCAL remains a prerequisite for submission of sponsored project proposals and IRB protocols.

24. **With respect to the P&S Policy, is there oversight of COI for students?** The Senior Associate Dean for Student Affairs provides oversight for COI involving P&S students. Where relevant, oversight will be performed jointly with the Vice Dean for Academic Affairs.

25. **Where can I obtain additional information?** For more information regarding the P&S COI Policy on Education and Clinical Care, contact the Office of Academic Affairs at: ps-coi@columbia.edu 212-305-4601. The policy and additional information are posted at: www.cumc.columbia.edu/faculty/coi. For additional information and links to the University's other COI policies, including COI in research, please visit the Research Compliance and Training website at: www.researchcompliance.columbia.edu or call 212-851-1996.

26. **How do I get help with RASCAL?** For RASCAL technical assistance, you can email rascal@columbia.edu or call the Rascal Helpline: (212) 851-0213. If you have never logged into RASCAL, you may be presented with a Personal Information page to complete. Fill in the required fields (marked in red) and save.

CONTENT FAQs

(See the Introduction for some of the revised content for 2013.)

1. **What financial interests/revenues need to be disclosed under the P&S COI Policy? Do revenues from consultation, presentations and committees need to be**

disclosed? The requirement of disclosure pertains to financial interests in any Business related in any way to your clinical or teaching responsibilities at Columbia. For example:

- **Consulting income and fees from industry-sponsored presentations:** income from these sources must be disclosed. Faculty and Researchers are responsible for the intellectual integrity of their presentations and materials, and thus are encouraged to identify the funding source for their external presentations.

- **Income for part time Faculty in private medical practice:** Part time Faculty need not disclose income from their private medical practice.

- **Disclosure is required for all commercial payment in any amount,** removing the \$10k threshold for disclosure. This “zero threshold” for disclosure is congruent with C.U.’s research COI policy and with the policies of peer institutions.

2. **Ghost writing:** (this practice is described as “Ghost writing and ghost authorship”) and is specifically forbidden. Faculty and Researchers are required to notify journals, edit CVs, etc. to correct for uncredited commercial writers.

3. **What other income must be disclosed?**

- Fees for medical-legal expert consultation must be disclosed.

- Equity holdings, stock and stock options, royalties or license fees must be disclosed– see definitions on the disclosure form.

- Directorship or executive positions in a Business must be disclosed.

- Mutual funds do not require disclosure or review if they are managed by a third party, if the Faculty or Researcher or members of his/her immediate family do not make investment decisions for the fund.

- Income from academic/governmental/non-profit service functions, such as serving in an advisory capacity and giving non-commercially supported presentations, does not need to be disclosed.

- Income from personal activities that are completely unrelated to a Faculty or Researcher’s professional activities or identity does not need to be disclosed.

4. **Does reimbursement for travel expenses need to be disclosed?** Commercial support for travel expenses, if for legitimate professional activities, do not require disclosure. Commercial support of travel should be reasonable and of a modest standard (i.e., not lavish). Travel must be in accordance with Columbia’s Travel and Entertainment Policy.

5. **Can slides or materials generated by commercial entities be used in public presentations?** Slides, materials or data should be independent of commercial influence, except where prescribed by law (e.g. FDA requirements for the presentation of materials or data relevant to approval of drugs and/or devices prepared by commercial entities). Presentations using commercial sources must indicate those slides, tables, data or other materials that are provided by commercial entities or their agents. Faculty and Researchers are expected to convey that their presentations reflect their own work and views, and do not represent views held by Columbia University or its affiliates. Use of the Columbia name, logo or images in presentations or associated materials is prohibited, except to identify Faculty and Researchers by their University title, and cannot be used for co-branding.

6. **Industry-sponsored Presentations:** Participation in engagements where a Columbia University Faculty or Researchers gives a presentation that is designed and/or approved by a sponsoring commercial entity or its agent concerning the company’s products or services (formerly referred to as membership in a “Speakers’ Bureau”) is generally prohibited. Faculty and Researchers are prohibited from speaking for industry if the arrangement has one or more of the following characteristics:

a. A commercial entity (or its agent) dictates or controls content, or has final approval of a presentation;

b. Faculty and Researchers are expected to act as an agent or spokesperson for a commercial entity (or its agent) for the purpose of marketing;

c. The sponsor (or its agent) creates the presentation and expects the use of their language for the presentation.



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