

Appendix L

CPMC Conflict of Interest Policy

The CPMC Conflict of Interest Policy was approved by the Executive Committee of the Faculty Council on March 8, 1993 and by the Faculty Council of the Faculty of Medicine on April 26, 1993 and December 12, 1994.

Columbia University Health Sciences and The Presbyterian Hospital in the City of New York

Introduction

This Revised Policy is to comply with Public Health Service Policy (8-18, 8-19 revised 4/1/94) which states:

Recipient organizations must establish safeguards to prevent employees, consultants or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties. Therefore, each institution receiving financial support must have written policy guidelines on conflict of interest and the avoidance thereof.

This policy is intended to serve as a guide for Faculty (footnote no. 1), employees, consultants or members of the governing bodies of the College of Physicians and Surgeons, the School of Dental and Oral Surgery, the School of Public Health, the School of Nursing, and Affiliated Hospital Staff (footnote 2) Members both full and part-time, in structuring their relationships with industry and other outside ventures in view of their academic responsibilities for teaching, research, and patient care. An integral part of the policy is a disclosure mechanism whereby Faculty and Affiliated Hospital Staff Members regularly report on their activities. The policy is not intended to address conflicts of commitment, which are governed by other University and Hospital policies.

A Faculty and/or Affiliated Hospital Staff Member is considered to have a conflict of interest when he/she (footnote 3), any of his Family, or any Associated Entity possesses a Financial Interest in an activity or Business which may have an inappropriate influence, or appear to have such an influence, on his activities as a member of the Faculty or Affiliated Hospital Staff. Included in these responsibilities are all activities in which the Faculty or Affiliated Hospital Staff Member is engaged in the areas of teaching, research, patient care, or administration.

Category I—Activities Which Are Not Ordinarily Allowable

Research Activities

- (a) A Faculty or Affiliated Hospital Staff Member may not without prior permission by the Standing Committee participate in research, including clinical trials, on a Technology owned by or contractually obligated (footnote 4) to a Business in which the Faculty or Affiliated Hospital Staff Member, a member of his Family, or an Associated Entity has a Financial Interest, other than royalties and/or licensing fees under institutional agreements.
- (b) A Faculty or Affiliated Hospital Staff Member may not receive University or Affiliated Hospital Sponsored Research support for research from a Business in which he, a member of his Family, or an Associated Entity has a Financial Interest.
- (c) Faculty or Affiliated Hospital Staff Members without prior permission from the Joint Standing Committee (see below) may not assign students, post-doctoral fellows or other trainees to projects sponsored by a Business in which the Faculty and/or Affiliated Hospital Staff Member, a member of his Family, or an Associated Entity has a Financial Interest.

External Activities

- (a) Committee Participation—Faculty or Affiliated Hospital Staff Members serving on a committee of the FDA, other governmental or non-governmental agencies, or private insurers, may not Participate without prior disclosure to and with the expressed consent of the “agency,” in the deliberations or recommendations by such a committee on a Technology which is owned by or contractually obligated (footnote 5) to a Business in which that Faculty or Affiliated Hospital Staff Member, a member of his Family, or an Associated Entity has a Financial Interest.
- (b) A full-time Faculty or Affiliated Hospital Staff Member may not assume an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature.
- (c) A Faculty or Affiliated Hospital Staff Member may not make clinical referrals except for procedures carried out in his/her own office to a Business in which such Faculty or Affiliated Hospital Staff Member, a member of which his Family, or an Associated Entity has a Financial Interest without prior disclosure and permission of the Standing Committee.

Administrative Responsibilities

- (a) A Faculty or Affiliated Hospital Staff Member may not take administrative action within the University or Affiliated Hospital without prior disclosure and permission of the Standing Committee which is likely to benefit a Business in which he or a member of his Family or an Associated Entity has a Financial Interest.

- (b) A Faculty, Affiliated Hospital Staff Member or University Administrative Officer may not participate in or otherwise influence the selection by the University and/or Hospital of a contractor, vendor or supplier of goods or services that the Staff Member or a member of his Family or an Associated Entity has a Financial Interest.
- (c) A Faculty or Affiliated Hospital Staff Member may not Participate in or otherwise influence any University and/or Hospital transaction without prior disclosure and permission of the Standing Committee to buy, sell, lease or license real or intellectual property in which the Staff Member or a member of his Family or an Associated Entity has a Financial Interest.

Category II—Allowable Activities Which Must Be Disclosed

Public Disclosure

A Faculty or Affiliated Hospital Staff Member publishing or formally presenting research results, or providing expert commentary on a subject, including by participation in a Continuing Medical Education program, must simultaneously disclose any Financial Interest relating to such results or such subject.

Board Memberships

A Faculty or Affiliated Hospital Staff Member may, with prior approval of the Standing Committee, serve on the Board of Directors or Scientific Advisory Board of a Business provided that the Faculty or Affiliated Hospital Staff Member or a member of his Family, or Associated Entity does not receive University or Affiliated Hospital supervised Sponsored Research support from that Business.

Activities Conducted Pursuant to Consulting Agreements or While on Sabbatical or Other Leave

A Faculty or Affiliated Hospital Staff Member may, with prior disclosure, engage in consulting for commercial organizations as long as such consulting is consistent with University and any applicable Hospital guidelines governing consulting (footnote 6), provided that the Consulting obligations have no objectionable directional influence on teaching, research, or patient care activities.

This Policy is not intended to limit the rights of Faculty or Affiliated Hospital Staff Members to conduct research at other institutions while on sabbatical or other leave from the University and/or Affiliated Hospital. Such activities, however, should be disclosed in advance to the Dean and appropriate Departmental Chairman at the University, and/or the Executive Vice President and Chief Medical Officer of the Affiliated Hospital, and are subject to the guidelines governing such research that the University and Affiliated Hospitals may have in place.

Teaching and Patient Care

Faculty and/or Affiliated Hospital Staff Members, without prior permission, may not participate in teaching or patient care activities involving a Technology sponsored by a Business in which the Faculty and/or Affiliated Hospital Staff Member, a member or his Family, or an Associated Entity has a Financial Interest.

Appendix A: Operating Definitions

Associated Entity

- (a) An “**Associated Entity**” of a Faculty or Affiliated Hospital Staff Member means any trust, organization or enterprise other than the University or any Affiliated Hospital over which the Faculty or Affiliated Hospital Staff Member, alone or together with his Family, exercises a controlling or significant interest.

Business

- (b) “**Business**” means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, Business, or real estate trust, or any other legal entity organized for profit.

Executive Position

- (c) “**Executive Position**” refers to any salaried position which includes responsibilities for a material segment of the operation or management of a Business.

Faculty Member

- (d) “**Faculty Member**” includes, for the purposes of this Policy, anyone who is a Health Sciences officer, including officers Emeriti employed by the University.

Affiliated Hospital Staff Member

- (e) “**Affiliated Hospital Staff Member**” includes: attending physicians, associate attending physicians, assistant attending physicians, instructors, clinical fellows.

Family

- (f) The “**Family**” of a Faculty or Affiliated Hospital Staff Member includes his spouse, minor children, and any other immediate Family member, e.g., sibling, parent(s), or adult child, whose financial holdings are known to the Faculty or Affiliated Hospital Staff Member. This includes *de facto* spouses.

Financial Interest

- (g) A “**Financial Interest**” is a significant interest in a Business consisting of any stock, stock option or similar ownership interest in such Business which if disclosed would appear to create a Conflict of Interest, but excluding any interest arising solely by reason of investment in such Business by a mutual, pension or other institutional investment fund over which the Faculty or Affiliated Hospital Staff Member does not exercise control.

Participate

- (h) “**Participate**” means to be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, research collaborator, teacher or provider of direct patient care. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of clinical research, to the trial participants, unless they are in a position to influence the study’s results or have privileged information as to the outcome.

Sponsored Research

- (i) “**Sponsored Research**” means research, training and instructional projects involving funds, materials, or other compensation including gifts from outside sources.

Technology

- (j) “**Technology**” means any methodology, information, compound, drug, device, diagnostic, medical or surgical procedure intended for use in health care or health care delivery, or biomedical research.

Appendix B: Implementation For All Health Sciences Officers and Staff Members of The Presbyterian Hospital***Joint Standing Committee on Conflicts of Interest***

The Dean of the Faculty of Medicine and the Executive Vice President and Chief Medical Officer of The Presbyterian Hospital will appoint a Joint Standing Committee on Conflicts of Interest to be comprised of representatives from both the clinical and pre-clinical Faculty. The Chairman of the University Science and Technology Policy Committee shall serve as a permanent member (but not Chairman) of the Joint Standing Committee. A representative from the University’s Office of the General Counsel and a representative from the Office of Corporate and Legal Affairs of The Presbyterian

Hospital shall serve as *ex-officio* members of the Joint Standing Committee. Senior Administrative officers of each of the four schools shall serve as *ex-officio* members of the Committee. This Administrative group will conduct an initial review of all completed disclosure forms and attempt to resolve any potential problems. Any issues/problems that cannot be resolved will be referred to the full Standing Committee for solution. At the Standing Committee's regular meetings, the committee would be apprised of the actions taken by the administrative group. All issues relating to general policy would not be handled by the administrative group but would reside with the main committee.

The Committee will be responsible for disseminating, collecting and reviewing completed disclosure forms that are required to be completed by Faculty and Presbyterian Hospital Staff Members, as well as any other potential Conflict of Interest brought to its attention by faculty, staff or administration. It will conduct thorough reviews of potential Conflicts and will make recommendations for conflict resolution to the Dean and/or Executive Vice President and Chief Medical Officer of The Presbyterian Hospital. In all cases involving a member of the Faculty of Medicine, the Dean will promptly provide a copy of such report for review by the Vice Provost for Science and Engineering. No reports need to be made to the Hospital with respect to Faculty Members with no Hospital appointment, and no reports need to be made to the University with respect to Hospital Staff Members who have no University appointment.

The Committee will develop a procedural document to guide its activities, as well as an associated timetable to review disclosure forms, and process instances involving non-compliance and breach.

The Joint Standing Committee will have jurisdiction over all breaches of the Conflict of Interest Policy and disclosure process, including (a) failure to comply with such process, whether by virtue of a Faculty or Presbyterian Hospital Staff Member's failure to complete and submit to the Committee the disclosure form or by his responding with incomplete or knowingly inaccurate information, (b) failure to remedy a Conflict, and (c) failure to comply with a prescribed monitoring plan. In all cases, Faculty or Presbyterian Hospital Staff Members will be provided the explicit opportunity to respond in person and in writing to the issues raised in the course of such review. Any such written response will be appended to the Committee's report for review by the Dean and the Vice Provost for Science and Engineering and/or the Executive Vice President and Chief Medical Officer of The Presbyterian Hospital.

Included in the reports described above shall be recommendations for sanctions and disciplinary actions to be taken by the Dean and Vice Provost for Science and Engineering and/or the Executive Vice President and Chief Medical Officer of The Presbyterian Hospital.

Procedures for Disclosure and Review and Actions to be Taken

Submission of Disclosure Forms

Each Faculty and Presbyterian Hospital Staff Member will be required to complete and submit a disclosure form to the Committee at the time of appointment or promotion or grant application process and to amend the disclosure form when necessary to reflect any changed circumstances that could give rise to a Conflict of Interest as defined in this Policy. Such amendments are to be made within thirty (30) days of the change in circumstance. The disclosure form will be considered strictly confidential, and it will be the responsibility of the Joint Standing Committee to ensure that the information disclosed on the form is available only to the individuals duly charged with the responsibility for review.

Review of Disclosure Forms

Following the receipt of the disclosure forms, the Committee, in a timely manner, will review the disclosures and identify breaches of the disclosure process and/or the existence of a Conflict of Interest. The Faculty Member or Presbyterian Hospital Staff Member will be notified of any such breach of compliance or Conflict and be given the opportunity to take corrective action within a specified period of time. If such corrective action is not taken, the Committee will provide a report to the Dean and/or Executive Vice President and Chief Medical Officer of The Presbyterian Hospital setting forth the nature of the breach and the recommended sanctions to be taken. Promptly upon receipt the Dean will provide copies of all such reports concerning members of the Faculty of Medicine to the Vice Provost for Science and Engineering. It will be the responsibility of the Dean in consultation with the Vice Provost for Science and Engineering and/or the Executive Vice President and Chief Medical Officer of The Presbyterian Hospital to take the necessary disciplinary actions, some of which may require approval by the President and Board of Trustees of the University, and/or the President and Board of Trustees of The Presbyterian Hospital.

Sanctions and Actions to Be Taken

Possible sanctions and disciplinary actions may include the following:

- (a) The inclusion in the Faculty or Presbyterian Hospital Staff Member's file of a letter from the appropriate University and/or Hospital officials indicating that the individual's good standing as a member of the Faculty or Presbyterian Hospital Staff has been called into question, i.e., censure.
- (b) Ineligibility of the Faculty or Presbyterian Hospital Staff Member for sponsored project applications, to teach or organize Continuing Medical Education programs, Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval, or supervision of graduate students.
- (c) Non-renewal of appointment.
- (d) Dismissal from the University and/or The Presbyterian Hospital Staff.

Right of Appeal

Faculty members will have the right to appeal to the Provost all sanctions proposed by the Dean of the Faculty of Medicine. Presbyterian Hospital Staff members will have the right to appeal to the President of The Presbyterian Hospital all sanctions proposed by the Executive Vice President and Chief Medical Officer.

Footnotes**Footnote No. 1**

For the purposes of this policy, Faculty shall be defined to include all Health Sciences Officers, including Officers Emeriti employed by the University. For the definitions of other capitalized terms used in this Policy, see Appendix A.

Footnote No. 2

Affiliated Hospital Staff shall be defined to include only affiliated staff members located at The Presbyterian Hospital.

Footnote No. 3

Masculine parts of speech are hereafter presumed to include the feminine.

Footnote No. 4

By license or exercise of an option to license.

Footnote No. 5

By license or exercise of an option to license.

Footnote No. 6

For example, Faculty Members may engage in outside consulting work no more than one day a week.

POLICY DISTRIBUTION DATE

Printed for distribution: 7/17/95

Addendum to Conflict of Interest Policy and Disclosure Form

DEFINITIONS OF “FINANCIAL” INTEREST AND “FAMILY”

Change “Financial Interest” to “Significant Financial Interest.”

A “Significant Financial Interest” is anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests) and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the University or The Presbyterian Hospital;

(2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(3) Income from service on advisory committees or review panels for public or nonprofit entities;

(4) An equity interest that when aggregated for the Faculty or Affiliated Hospital Staff Member and his Family members meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership interest in any single entity; or

(5) Salary, royalties or other payments that when aggregated for the Faculty or Affiliated Hospital Staff Member and his Family Members over the next twelve months, are not expected to exceed \$10,000.

The “Family” for purposes of this policy includes your spouse or domestic partner, your brothers or sisters (whether by whole or half blood) or those of your spouse or domestic partner, your ancestors, children, grandchildren, great grandchildren, and the spouses of your children, siblings, grandchildren, and great grandchildren.