

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
Policy on Conflicts of Interest in Clinical Care
Approved by FPP Board of Directors: March 16, 2006

I. Purpose

The Washington University School of Medicine and its physicians recognize that the best interest of the patient is paramount and acknowledge their commitment to altruism, scientific integrity and the absence of bias in medical decision making. Washington University and its physicians are committed to avoiding conflicts of interest or the appearance of conflicts of interest between their financial interests and the best interests of their patients. It is also recognized that Washington University physicians, as highly trained specialists, have a unique opportunity to improve and advance patient care through collaboration with industry. By adopting this Conflict of Interest in Clinical Care policy, the School of Medicine and its physicians demonstrate their commitment to establishing a disclosure and review process to safeguard University and physician integrity and objectivity, such that collaborations with industry can optimally benefit patients.

Accordingly, Washington University's policy is to ensure full disclosure of financial relationships, as defined below ("Financial Relationship"), between its physicians and commercial companies that manufacture, distribute or otherwise provide medical devices, implants, pharmaceuticals or other medical care related products ("Commercial Companies") that may be utilized in the care of Washington University patients.

Washington University considers a potential conflict of interest to exist when a Washington University treating physician (or his/her immediate family member) has a material Financial Relationship with a Commercial Company, and the physician is in a position to affect a patient's decision and/or consent to the use of that manufacturer's, distributor's or entity's product.

(Note: This policy does not apply to ancillary equipment whose use does not generally require a patient's consent, even though the equipment may be utilized during a patient's medical treatment, e.g. scissors, sutures, staples.)

II. Policy

Washington University recognizes that its physicians are often the best qualified clinicians to provide Commercial Companies with innovative ideas and product feedback, to conduct clinical research, to serve on scientific advisory boards, and to serve as faculty to teach the use of new technologies. Additionally, Washington University physicians often rely on Commercial Companies to bring their creative ideas to fruition. These collaborative relationships with industry are vital to advancing and improving patient care and treatment. It is also recognized that it is appropriate for physicians to receive reasonable compensation for the

services they provide to these Commercial Companies. However, Washington University and its physicians acknowledge that these relationships must also be carefully scrutinized to avoid improper inducements, whether real or perceived, and that patients be advised of these relationships where that information is pertinent to informed consent.

i) Acceptable Payments

Physicians who provide services to Commercial Companies should receive reasonable compensation for their services. However, to avoid the appearance of an improper inducement, Washington University physicians who collaborate or otherwise provide services to Commercial Companies shall comply with the following:

- a. Ensure that collaborations are performed pursuant to a written agreement or memorandum that is established in advance with a description of the expected deliverables. It is recognized that it may not always be practicable to establish a written agreement in advance; however, as soon as feasible the collaboration should be reduced to writing. Additionally, pursuant to University policy, the agreement or memorandum should include Commercial Company's acknowledgement and understanding that the physician is acting solely in his/her individual capacity and not as an agent or representative of Washington University, and that Washington University assumes no liabilities or obligations under the collaboration.
- b. Maintain documentation of the compensation received and the services provided, including reasonable estimates of the time and effort committed to providing the services.
- c. Ensure that compensation is based on the provision of tangible services and not on the decision to use a specific device, implant or drug in a patient.

On an institutional level, Washington University departments and divisions may accept unrestricted educational grants from Commercial Companies, when such support is not directed to an individual physician, provided that such grants are used to support the educational, research or clinical care missions of the institution.

ii) Unacceptable Payments

No payments to Washington University physicians should be based on the use of a particular device, implant or drug in a patient. In the case of product royalties, physicians will refrain from collecting royalties based on the use of their product in Washington University patients.

Additionally, Washington University physicians who engage in clinical care will refrain from accepting gifts from Commercial Companies. Gifts are those items or services of value received from Commercial Companies gratuitously and not in exchange for legitimate services. Gifts from Commercial Companies that should not be accepted include, but are not limited to, cash payments, free goods, free travel, free accommodations, payment of meeting registrations or payment for participation in on-line CME's.

iii) University Disclosure

Washington University physicians who engage in clinical care will disclose their Financial Relationships with Commercial Companies to the University on an annual basis, and will update their disclosures immediately upon entering a new or revised Financial Relationship. The University will establish a process to review and manage potential conflict of interest.

iv) Patient Disclosure

If a Washington University physician has a material Financial Relationship with a Commercial Company that manufactures permanently implantable medical devices, the physician must disclose to his/her patients this Financial Relationship before obtaining the patient's consent to utilize the device in that patient. Such disclosure shall be documented in the patient's medical record.

Other material Financial Relationships with Commercial Companies may also warrant patient disclosure before a Washington University physician recommends, prescribes or uses that company's medical device, pharmaceutical or medical care related product in his/her patients.

Financial Relationships requiring patient disclosure will be determined by the Associate Vice Chancellor for Clinical Affairs, in consultation with the Dean, the Office of the Executive Vice Chancellor and General Counsel and the Faculty Practice Plan's Professional Liability Committee.

v) Definitions

Financial Relationship: For purposes of this policy, a Financial Relationship is any relationship in which a Washington University faculty member (or his/her immediate family member) has received, or

is expected to receive, cash or something of value, including but not limited to consulting fees, advisory board payments, product evaluation payments, royalties, intellectual property rights, honoraria, ownership interests (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds), educational payments, unrestricted grant awards, or other financial benefit, from a company, person or entity that produces, manufactures or distributes a medical device, implant, pharmaceutical or other medical care related product that is recommended or prescribed to Washington University patients.

Immediate family member: For purposes of this policy, immediate family member includes a relative, in-law or domestic partner who has a Financial Relationship with a Commercial Company the product(s) of which are recommended, prescribed or used by the WU faculty member in the care of patients. Additionally, Washington University considers payments to a privately held company in which a Washington University faculty member (or his/her immediate family member) has an ownership interest to be payments to the faculty member.

III. Procedure

All Washington University physicians involved in clinical care must annually submit the Confidential Financial Disclosure Statement pursuant to the Disclosure Review Committee's Conflict of Interest policy. Only information specifically related to clinical conflicts of interest will be forwarded to the Associate Vice Chancellor for Clinical Affairs for review. The Confidential Financial Disclosure Statement must be updated immediately upon entering a new or revised Financial Relationship. The Associate Vice Chancellor for Clinical Affairs will review and manage potential conflicts of interest.

When directed as a management strategy Washington University physicians will disclose Financial Relationship(s) to their patients, or the patient's immediate family where appropriate, prior to obtaining the patient's consent for treatment with a device, implant, pharmaceutical or other medical care related product to avoid the appearance of inappropriately influencing the patient's medical decisions.

All Washington University physicians will provide copies of the documentation maintained pursuant to Section II (i) (a) and (b) of this policy to the Associate Vice Chancellor for Clinical Affairs upon request.

IV. Implementation and Enforcement

The Associate Vice Chancellor for Clinical Affairs will review faculty disclosures and manage and resolve potential clinical conflicts of interest in conjunction with

the appropriate Department Chair. The Associate Vice Chancellor for Clinical Affairs, in consultation with the Dean and the Office of the Executive Vice Chancellor and General Counsel, will determine the thresholds for management of potential conflicts of interest, as well as the management strategies to be employed by the University.

Disclosures may be referred to a standing review committee if management of a conflict of interest can not be resolved between the Associate Vice Chancellor for Clinical Affairs and the appropriate Department Chair. The members of the Review Committee shall be appointed by the Dean, and will include two senior medical school faculty members and a senior medical school administrator, with counsel from the University's Office of the Executive Vice Chancellor and General Counsel, as required. The Review Committee shall develop procedures to promptly evaluate faculty conflict of interest and if a conflict is identified shall share its written conclusions and recommendations with the faculty member and his/her Department Chair.

Whenever appropriate, the Review Committee, or when necessary, the Dean or his/her designee, shall attempt to resolve or manage the conflict situation in a manner appropriate and reasonable to the individual situation by obtaining the faculty member's cooperation in the implementation of the recommendations. The resolution of an identified conflict of interest will be recorded by the Review Committee.

V. Remedial Action

If after thirty (30) days, the conflict of interest has not been resolved in accordance with the foregoing, the University may:

- i) Suspend the faculty member's clinical privileges
- ii) Withdraw professional liability insurance coverage for the faculty member
- iii) Reduce the faculty member's salary or bonus, and/or
- iv) Take other actions as deemed appropriate.