

**WASHINGTON UNIVERSITY SCHOOL OF MEDICINE**  
**Policy on Conflicts of Interest in Clinical Care**  
**Approved by FPP Board of Directors: March 16, 2006**  
**Revised and Approved by FPP Board of Directors: December 15, 2009**

**I. Purpose**

The Washington University School of Medicine and its physicians and health professionals 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 and health professionals are committed to avoiding conflicts of interest or the appearance of conflicts of interest between their individual financial interests and the best interests of their patients. It is also recognized that Washington University physicians and health professionals, 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 and health professionals demonstrate their commitment to establishing a disclosure and review process to safeguard University and individual 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 health professionals, and Commercial Health Care companies that manufacture, distribute or otherwise provide medical devices, implants, pharmaceuticals or other medical care related products and services ("Commercial Health Care 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 health professional (or his/her immediate family member) has a material Financial Relationship with a Commercial Health Care Company, and the physician or health professional 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 and allied health professionals are often the best qualified clinicians to provide Commercial Health Care 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 and health professionals often rely on Commercial Health Care 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 and health professionals to receive reasonable compensation for the services they provide to these Commercial Health Care Companies. However, Washington University and its physicians and health professionals 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 and health professionals who provide services to Commercial Health Care Companies should receive reasonable compensation for their services. However, to

avoid the appearance of an improper inducement, Washington University physicians and health professionals who collaborate or otherwise provide services to Commercial Health Care 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 Health Care Company's acknowledgement and understanding that the physician or health professional 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, and commensurate with, 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, divisions and programs may accept unrestricted educational grants from Commercial Health Care Companies, when such support is not directed to an individual physician or health professional, provided that such grants are used to support the education, research or clinical care missions of the institution.

## **ii) Unacceptable Payments**

No individual payments to Washington University physicians or health professionals should be based on the use of a particular device, implant, pharmaceutical or other medical care related product or service in a patient. In the case of product royalties, physicians or health professionals will refrain from collecting royalties based on the use of their product in Washington University patients.

No individual payments to Washington University physicians or health professionals should be based on the performance of commitments to Washington University, such as teaching in the operating rooms of University-affiliated hospitals, patient care activities, research conducted under the auspices of Washington University (e.g. conducted with significant University resources or pursuant to a research grant or contract administered by the University), and authorship of journal articles or presentations reporting the results of such research.

Additionally, Washington University physicians and health professionals who engage in clinical care will refrain from accepting gifts from Commercial Health Care Companies. Gifts are those items or services of value received from Commercial Health Care Companies gratuitously and not in exchange for legitimate services. Gifts from Commercial Health Care 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 and health professionals who engage in clinical care will disclose their Financial Relationships with Commercial Health Care Companies to the University on an annual basis, and will update their disclosures immediately upon entering a new or revised Financial Relationship. The University has established a process to review and manage potential conflict of interest.

### **iv) Patient Disclosure**

If a Washington University physician or health professional has a material Financial Relationship with a Commercial Health Care Company that manufactures permanently implantable medical devices, the physician or health professional 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 or health professional 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) Public Disclosure**

Transparency regarding industry relationships is an important mechanism for preserving public trust and professional integrity. Accordingly, the following information will be posted on the WUSM Faculty Practice Plan web site for faculty members earning >\$10,000 per year or receiving equity from an industry relationship:

- a. Names of companies with whom faculty member has a financial relationship
- b. Basis for payments (ex: consulting, educational lectures, royalties, equity or stock options, etc)
- c. Range of reimbursement for most recent 12 month period

The threshold for public disclosure on the WUSM Faculty Practice Plan website may be revised at the discretion of the Faculty Practice Plan.

### **vi) Industry-Supported Educational Lectures**

Faculty must adhere to the following guidelines when giving educational lectures that are supported by industry:

- a. All financial support by industry must be reported to, and fully disclosed by, the meeting sponsor.
- b. Speakers must have sole editorial discretion as to lecture content and materials.
- c. Speakers must provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational discourse.

- d. Speakers should make it clear that the lecture content reflects their individual views and not the views of WUSM or its affiliated teaching hospitals.
- e. Use of the Washington University name in non-University events sponsored by Commercial Health Care companies should be limited to identifying the speaker by his/her title and affiliation.
- f. Powerpoint presentations, slides, handouts, brochures, flyers, mail and email announcements of industry-sponsored lectures cannot be co-branded using Washington University symbols, logos or images.
- g. Presentations that provide information related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or investigational nature of their proposed uses to the audience.
- h. Individual agreements with industry for educational lectures must be for a finite term not to exceed 5 [five] years.

### vii) 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 Health Care 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 and health professionals involved in clinical care must annually submit the Confidential Financial Disclosure Statement pursuant to the Disclosure Review Committee's Conflict of Interest policy. Annual Financial Disclosure Statements will be reviewed by the individual's department head. 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 and health professionals 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 and health professionals 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 or Program Director. 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 or Program Director. 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 or Program Director.

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:

- a. Suspend the faculty member's clinical privileges
- b. Withdraw professional liability insurance coverage for the faculty member
- c. Reduce the faculty member's salary or bonus, and/or
- d. Take other actions as deemed appropriate.

References:

<https://fpp.wusm.wustl.edu/fppolicies/Pages/PharmaceuticalMedicalDeviceIndustry.aspx>