



# Washington University Physicians

Washington University School of Medicine in St. Louis

## Policy on Conflicts of Interest in Clinical Care

Approved by FPP Board of Directors: March 16, 2006

Revised and Approved: December 15, 2009, January 18, 2011, January 22, 2013,  
January 21, 2014, April 18, 2017

### I. Purpose

Washington University in St. Louis (“University”) and the Washington University School of Medicine (“WUSM”), its Physicians and Health Professionals recognize that the best interest of the patient is paramount and commit to altruism, scientific integrity and to minimize bias in medical decision making. WUSM and its Physicians and Health Professionals commit 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 Physicians and Health Professionals, as highly trained specialists, have a unique opportunity to improve and advance patient care and support the mission of the University through collaboration with industry. By adopting this Policy on Conflict of Interest in Clinical Care, WUSM, Physicians and Health Professionals demonstrate their commitment to establishing a disclosure and review process to promote integrity and objectivity in clinical care, such that collaborations with industry can optimally benefit patients.

Accordingly, WUSM’s policy is to ensure full disclosure of Financial Relationships between Physicians and Health Professionals, and industry.

WUSM considers a potential conflict of interest to exist when a Physician or Health Professional (or his/her Immediate Family Member) has a Financial Relationship with an Entity, and the Physician or Health Professional is in a position to affect a patient’s decision and/or consent to the use of that Entity’s products or services.

(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. Definitions

“**Entity**” means a person, company, partnership or organization that produces, manufactures, distributes or otherwise provides medical devices, implants, pharmaceuticals or other medical care related products and services that may be utilized in the care of WUSM patients or that serves as an agent or intermediary for such company, partnership or organization.

“**Consulting**” means advising, scientific or advisory board services, governing board services, product evaluation, case evaluation, speaking, legal consulting, and expert witness services provided on behalf of an Entity. Consulting does not include expert witness services related to medical malpractice litigation; however, such services must comply with the requirements of the Policy for Expert Witness Testimony.

“**Fair Market Value**” means compensation that is commensurate with the provision of the services rendered, but in any case, not more than \$550/hour for Consulting or in the case of speaking services, not more than \$550/hour or \$3,000 per talk/lecture, which amount may be

revised from time to time by the Associate Vice Chancellor for Clinical Affairs based on AAMC faculty compensation benchmark data.

**“Financial Relationship”** means any relationship in which a Physician or Health Professional (or his/her Immediate Family Member) has received, or is expected to receive, cash or something of value, directly or indirectly, including but not limited to Consulting fees, royalties, intellectual property rights, honoraria, ownership interests (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds and publicly traded stock of less than 5%), educational payments, unrestricted grant awards, or other financial benefit, from an Entity. Payments to a privately held company in which a Physician or Health Professional (or his/her Immediate Family Member) has an ownership interest are considered payments to the Physician or Health Professional.

**“Health Professional”** means WUSM nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, occupational therapists, physical therapists and pharmacists.

**“Family Member”** means spouse, domestic partner and dependent children.

**“Physician”** means any physician who has a full or part-time appointment with WUSM and fellows. It does not include voluntary faculty.

### III. Policy

WUSM recognizes that Physicians and Health Professionals are often the best qualified clinicians to provide Entities with innovative ideas and product feedback, conduct clinical research, serve on scientific advisory boards, and serve as faculty to teach the use of new technologies. Physicians and Health Professionals often rely on Entities to bring their creative ideas to fruition. These collaborative relationships with Entities 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 Entities. However, Physicians and Health Professionals acknowledge that these relationships must be carefully scrutinized and managed to avoid improper inducements, whether real or perceived, to assure that patients are advised of these relationships through informed consent and to avoid direct or implied endorsement by WUSM of non-University products or services.

This policy applies to Physicians and Health Professionals in all clinical settings regardless of practice location.

#### A. Acceptable Payments

1. Services: Compensation for Consulting must be consistent with Fair Market Value.
2. Royalties: Compensation for royalties must be set forth in an agreement that describes the invented or authored royalty bearing intellectual property claimed in a patent application or issued patent, or protected by copyright, if software. Records or the agreement itself should provide a specific and detailed identification of the intellectual property on which royalties will be paid, including the patent number, patent application serial number or copyright registration number.

Compensation for royalty bearing intellectual property that is not the subject of a patent, patent application or copyright is permitted only if:

- (a) A written and detailed description of the process used by the Entity to confirm a verifiable and valuable contribution of intellectual property to the design and/or development of the royalty-bearing product; and

- (b) An attestation based upon the findings of that process that the royalty rate being paid is consistent with the fair market value of such intellectual property.
3. Equity: Compensation in the form of equity (preferred and common stock, stock options, including warrants, bonds and notes) must be at no more than Fair Market Value for the services rendered at the time of issuance.

## **B. Unacceptable Payments**

Payments may not 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 and Health Professionals may not collect royalties based on the use of the product in any WUSM patient.

Payments may not be based on the performance of commitments to WUSM, such as teaching in the operating rooms of WUSM-affiliated hospitals, patient care activities, research conducted under the auspices of the University (e.g. conducted with 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.

## **C. Patient Disclosure**

Financial Relationships with Entities that manufacture permanently implantable medical devices and that exceed >\$10,000 per year or result in an ownership interest require the Physician or Health Professional to disclose to his/her patients the Financial Relationship before obtaining the patient's consent to utilize any of the Entity's implantable devices in that patient.

Financial Relationships with Entities that exceed >\$10,000 per year or result in an ownership interest also require patient disclosure before a Physician or Health Professional recommends, prescribes or uses any of the Entity's medical devices, pharmaceuticals, medical care related products or services with his/her patients.

Financial Relationships requiring patient disclosure will be managed by the Associate Vice Chancellor for Clinical Affairs.

## **D. Public Disclosure**

Transparency regarding Entity Financial Relationships is an important mechanism for preserving public trust and professional integrity. Accordingly, the following information will be posted on the WU Physicians website for Physicians and Health Professionals earning >\$10,000 per year or maintaining an ownership or potential ownership interest in an Entity:

1. Name of the Entity;
2. Basis for payments (e.g., Consulting, royalties, equity or stock options, etc.); and
3. Range of reimbursement for most recent 12 month period.

The threshold for public disclosure on the WU Physicians website may be revised at the discretion of the Faculty Practice Plan Professional Liability Committee.

## **E. Written Agreement**

To avoid the appearance of an improper inducement, Physicians and Health Professionals who collaborate or otherwise provide services to Entities, shall comply with the following:

1. Ensure that services are performed pursuant to a written agreement or memorandum that is established in advance describing the duties and obligations of each party, including the services provided by the Physician or Health Professional and the compensation to be paid by the Entity. It is recognized that it may not always be practicable to establish a written agreement in advance; however, as soon as feasible, the arrangement should be reduced to writing.
2. The agreement or memorandum must include the Entity'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 WUSM, and that WUSM assumes no liabilities or obligations under the collaboration. The following language must be included in all agreements and memoranda:

Notwithstanding anything herein to the contrary, Entity agrees that CONSULTANT serves Entity under this Agreement in his individual capacity, as an independent contractor, and not as an agent or representative of Washington University ("Institution"), that Institution exercises no authority or control over CONSULTANT while acting in such capacity, that Institution receives no benefit from such activity, that CONSULTANT and/or Entity cannot and will not make use of Institution resources or Institution managed funding in acting in such capacity, that Institution is not a party to this Agreement, and that Institution makes no representations or warranties under this Agreement and assumes no liability or obligation in connection with any such work or service undertaken by CONSULTANT. Entity further agrees that any breach, error, or omission by CONSULTANT acting in such capacity or otherwise under this Agreement, shall not be imputed or otherwise attributed to Institution. Moreover, nothing in this Agreement shall be read or understood to encumber, in any way, any intellectual property that Institution claims ownership of through the Institution's Intellectual Property Policy as such may be amended from time to time.

#### **F. Entity-Supported Educational Lectures**

Physicians and Health Professionals must adhere to the following guidelines when giving educational lectures that are supported by an Entity:

1. Physicians and Health Professionals must use best efforts to cause Sponsors to disclose in the course of the meeting or lecture any Financial Relationships with the Physician or Health Professional. Materials identifying speakers must include a written statement that the Physician or Health Professional is acting solely in his/her individual capacity on behalf of the Entity, not as an agent or representative of WUSM and must disclose whether compensation is being paid.
2. Physicians and Health Professionals must have final editorial discretion as to lecture content and materials. Physicians and Health Professionals may not participate as a presenter or panelist in Entity speakers' bureaus or other corporate-sponsored forums if the Entity controls what the speaker says or otherwise has the final approval rights over the speaker's presentation materials. Entity-provided content, materials and review necessary to ensure compliance with FDA regulations are acceptable, so long as the Physician or Health Professional retains editorial discretion over the remainder of the information presented. The agreement or correspondence engaging the speaking services of Physicians and Health Professionals must include the following language:

As speaker or panelist, (speaker) will have control over his/her own comments and content, except where compliance with FDA or other regulatory agency guidelines requires speakers to adhere to content that meets the agency's guidelines or proscriptions.

3. Physicians and Health Professionals must provide a fair and balanced assessment of



therapeutic options and promote objective scientific and educational discourse.

4. Physicians and Health Professionals should make it clear that the lecture content reflects their individual views and not the views of WUSM or its affiliated teaching hospitals.
5. Use of the University's name in non-University events sponsored by Entities should be limited to identifying the Physician or Health Professional by his/her title and affiliation.
6. PowerPoint presentations, slides, handouts, brochures, flyers, mail and email announcements of Entity-sponsored lectures cannot be co-branded using University symbols, logos or images.
7. 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 and must otherwise comply with any laws and regulations governing the promotion of such off-label uses.
8. Individual agreements for educational lectures must be for a finite term not to exceed 5 years.

#### **G. Documentation**

Physicians and Health Professionals should maintain documentation of the compensation received and the services provided, including reasonable estimates of the time and effort committed to providing the services and provide copies of the documentation to the Associate Vice Chancellor for Clinical Affairs upon request.

#### **H. Conflict of Commitment**

For purposes of this policy, WUSM considers it a conflict of commitment if Consulting services exceed one day a week or 560 hours annually.

Physicians and Health Professionals may not provide clinical or medical director services outside of WUSM without the prior written approval of the Associate Vice Chancellor for Clinical Affairs.

#### **I. Educational Grants**

For information about accepting unrestricted educational grants see Policy on Conflicts of interest in Clinical Care: Pharmaceutical and Medical Device Industry Policy: <https://fpp.wustl.edu/wp-content/uploads/2015/08/Clinical-Conflict-of-Interest-Policy-Pharma-and-Medical-Device-Industry-Policy-Rev-and-App-14.01.21.pdf>

#### **I. No Gifts**

For information about WUSM's no gifts policy, see Policy on Conflicts of interest in Clinical Care: Pharmaceutical and Medical Device Industry Policy: <https://fpp.wustl.edu/wp-content/uploads/2015/08/Clinical-Conflict-of-Interest-Policy-Pharma-and-Medical-Device-Industry-Policy-Rev-and-App-14.01.21.pdf>

#### **J. Use of Washington University's Name and Logos**

Physicians and Health Professionals may not wear University lab coats, badges or University apparel in conjunction with Consulting activities or use the University's name or trademarks without prior written approval of the Associate Vice Chancellor of Clinical Affairs in consultation with the Office of Public Affairs.

Generally, Physicians and Health Professionals are not authorized to use or offer the use of the University's names, trademarks, symbols, logos and images to any third parties that imply

or state an endorsement of any non-University products or services without the prior written approval of the Associate Vice Chancellor of Clinical Affairs.

#### **IV. Procedure**

Physicians and Health Professionals involved must annually submit a financial disclosure statement pursuant to the University's Research Conflicts of Interest Policy. Financial disclosure statements will be made available to the individual's Department Chair. Only information specifically related to clinical conflicts of interest will be forwarded to the Associate Vice Chancellor for Clinical Affairs for review. The financial disclosure statement must be updated within thirty (30) days of acquiring a new Financial Relationship in accordance with the requirements of the University's Research Conflict of Interest Policy. The Associate Vice Chancellor for Clinical Affairs will review and manage potential conflicts of interest.

#### **V. Additional Procedures for Health Professionals**

Health Professionals providing Consulting or other professional services to an Entity must obtain written approval from his/her Department Chair and the Associate Vice Chancellor for Clinical Affairs or his/her designee prior to providing such services, regardless of whether the Health Professional receives compensation, and must otherwise comply with the requirements of this policy. Approved Consulting activities should be performed outside of the Health Professional's scheduled work hours (e.g., weekends, holidays or vacation) in accordance with the WUSM Employee Handbook.

#### **VI. Implementation and Enforcement**

The Associate Vice Chancellor for Clinical Affairs will review 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 Office of the 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.

Disclosures may be referred to a Review Committee if management of a conflict of interest cannot be resolved between the Associate Vice Chancellor for Clinical Affairs and the Department Chair. The members of the Review Committee will be appointed by the WUSM 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 Vice Chancellor and General Counsel. The Review Committee is advisory to the WUSM Dean. The Review Committee will review documentation provided by the Associate Vice Chancellor for Clinical Affairs and the Physician or Health Professional and submit its findings to the WUSM Dean. The WUSM Dean may accept, reject or modify the Review Committee's finding to impose a management strategy that addresses the conflict of interest or conclude that there is no conflict of interest.

Whenever appropriate, the Review Committee, or when necessary, the WUSM Dean or his/her designee, shall attempt to resolve or manage the conflict situation in a manner appropriate and reasonable to the individual situation.

#### **VII. Remedial Action/Sanctions**

In the event a Physician or Health Professional fails to comply with this policy, disclose a Financial Relationship or comply with a management plan, the WUSM Dean may:

1. Suspend, restrict or terminate the individual's clinical privileges or ability to provide clinical care;
2. Withdraw professional liability insurance coverage;

3. Reduce the individual's salary or bonus;
4. Suspend, restrict or terminate the individual's consulting privileges; and/or
5. Take other actions as deemed appropriate.

## **Do's and Don'ts**

### **Do's**

- 1) Do comply with all University, WUSM and any other policies and guidelines for Consulting, including without limitation:
  - Policy for Expert Witness Testimony (<https://fppeducation.wusm.wustl.edu/QL/Policies/Expert-Witness-Testimony-Policy-04.07.15-Revised-2013.pdf>), and
  - Consulting Privileges policy (<https://facultyinformationhandbook.wustl.edu/consulting-privileges>), limiting faculty engagement in outside consulting to 20% of your time for an average of one day per week (560 hours/year).
- 2) Do make sure that your outside activities are consistent with the performance of all your University duties, including safeguarding the ability of you and other members of the University community to do present and future University research, education and clinical work free of conflicting commitments or obligations to third parties.
- 3) Do make sure all your Consulting arrangements, including all product development arrangements, are in writing and signed by the Entity. Do include a clearly defined scope of work in your Consulting agreement and the compensation that will be paid to you by the Entity. Do submit your agreements to the Associate Vice Chancellor for Clinical Affairs upon request or when completing your online financial disclosure statements.
- 4) Do remember that your Consulting obligations are yours and yours alone in your individual capacity and not as a WUSM employee or faculty member and may subject you to substantial personal liability. Do seek legal advice from your personal attorney for all your Consulting activities if you have any questions or are unsure of any obligation in such agreements. The Office of the Vice Chancellor and General Counsel may review Entity agreements for the sole purpose of determining compliance with University policy.
- 5) Do include the following language in all Consulting agreements clarifying the personal, non-institutional nature of such services:

“Notwithstanding anything herein to the contrary, Entity agrees that CONSULTANT serves Entity under this Agreement in his individual capacity, as an independent contractor, and not as an agent or representative of Washington University(“Institution”), that Institution exercises no authority or control over CONSULTANT while acting in such capacity, that Institution receives no benefit from such activity, that CONSULTANT and/or Entity cannot and will not make use of Institution resources or Institution managed funding in acting in such capacity, that Institution is not a party to this Agreement, and that Institution makes no representations or warranties under this Agreement and assumes no liability or obligation in connection with any such work or service undertaken by CONSULTANT. Entity further agrees that any breach, error, or omission by CONSULTANT acting in such capacity or otherwise under this Agreement, shall not be imputed or otherwise attributed to Institution. Moreover, nothing in this Agreement shall be read or understood to encumber, in any way, any intellectual property that Institution claims ownership of through the Institution’s Intellectual Property Policy as such may be amended from time to time.”
- 6) Do include the following language in all speaking agreements: “As speaker or panelist, (speaker) will have control over his/her own comments and content, except where compliance with FDA or other regulatory agency guidelines requires speakers to adhere to content that meets the agency’s guidelines or proscriptions.”
- 7) Do include a written statement in speaker materials that states that you are acting solely in your individual capacity on behalf of the Entity, not as an agent or representative of the University, and whether compensation is being paid to you by an Entity for providing speaker services.

- 8) Do comply with all aspects of the University's Intellectual Property Policy, including the obligation to disclose intellectual property to the Office of Technology Management, as necessary, so that the Office of Technology Management can make a "Rights Determination" and decide if the University can and will assert ownership of such intellectual property.
- 9) Do ensure and document that all compensation in whatever form (cash, equity, royalty, etc.) received is consistent with Fair Market Value for the services rendered or intellectual property transferred.
- 10) Do keep careful time records (activity logs) of all Consulting activities.
- 11) Do promptly and fully disclose all Consulting arrangements and other Financial Relationships with an Entity:
  - To your Department Chair;
  - On the annual financial disclosure statement and within thirty (30) days of acquiring a new Financial Relationship in accordance with the Research Conflict of Interest Policy;
  - To the IRB if engaged in human subject research;
  - To patients as required and in a form approved by the Associate Vice Chancellor for Clinical Affairs; and
  - In publications (journals, abstracts) and presentations at scientific meetings.

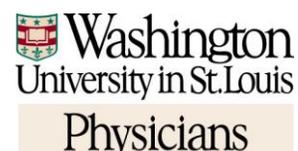
Disclosures should include:

- The Financial Relationship of the Physician or Health Professional and his/her Immediate Family Member
- If related to research, COI disclosures should include the financial interests of all individuals supported by company (fellows, residents, study coordinator, co-investigators, staff scientists, post docs and collaborators)

- 12) Do ensure that if you are promised royalties as all or part of your compensation in an agreement that:
  - Your invented or authored royalty bearing intellectual property is claimed in a patent application or issued patent, or protected by copyright, if software. Your records or the agreement itself should provide for the specific and detailed identification of the intellectual property on which you will be paid royalties by enumeration of the patent number, patent application serial number or copyright registration number; or,
  - If for royalty bearing intellectual property that is not the subject of a patent, patent application or copyright, you should not receive royalties as any part of your compensation unless the company provides: (a) a written and detailed description of the process used by the company to confirm that you have made a verifiable and valuable contribution of intellectual property to the design and/or development of the royalty-bearing product, and (b) an attestation based upon the findings of that process that the royalty rate being paid to you is consistent with the fair market value of such intellectual property.
  - You obtain and maintain records of royalty payments made to you, including the royalty rate and underlying sales figures.
- 13) Do comply with all University policies regulating the use of the University's names and symbols published by the Office of Public Affairs.

**Don'ts**

- 1) Don't accept compensation for Consulting services in excess of Fair Market Value.
- 2) Don't provide clinical or medical director services without the prior approval of the Associate Vice Chancellor for Clinical Affairs.
- 3) Don't accept royalties unless for products or services sold by the Entity that embody your



intellectual property as defined in a patent, patent application or copyright; or where you have obtained an Entity attestation of your contribution of intellectual property and its fair market value in terms of the royalty rate, as described above.

- 4) Don't accept royalty payments for your performance of defined services (e.g., Consulting, advisory, product review, etc.) provided to the Entity; royalties should only be for verifiable intellectual property that you have contributed to specific products and services.
- 5) Don't accept royalty payments that are based on a flat fee, or that are a minimum guaranteed amount.
- 6) Don't accept advances on royalties.
- 7) Don't accept royalty payments based on the use or sales of products or services provided to or in the care of WUSM patients.
- 8) Don't accept compensation for services, whether denominated as "consulting" or otherwise, involving the performance of your commitments to WU, such as:
  - Teaching (including preceptorships or visiting surgeons) in patient care areas or the operating rooms of University-affiliated hospitals
  - Patient care activities
  - Research conducted under the auspices of the University (e.g. conducted with significant University resources or pursuant to a research grant or contract administered by the University)
  - Authorship of journal articles published in non peer-reviewed or peer-reviewed journals reporting research conducted under the auspices of the University
- 9) Don't accept compensation for presentations of talks, abstracts or posters written solely by the Entity.
- 10) Don't wear Washington University lab coats, badges, or Washington University apparel in conjunction with Consulting activities.
- 11) Don't use the University's name(s) or symbol(s) to endorse or imply an endorsement of any non-University products or services without prior written approval of the Associate Vice Chancellor for Clinical Affairs and the Office of Public Affairs.

References/Helpful Links:

- University and Medical School consulting policies:  
[http://provost.wustl.edu/faculty\\_consulting](http://provost.wustl.edu/faculty_consulting)
- Use of Washington University's names and logos:  
<http://wustl.edu/policies/domain.html>  
<http://wustl.edu/policies/wustl-identity.html>

Policy for Expert Witness Testimony:

- <https://fpeducation.wusm.wustl.edu/QL/Policies/Expert-Witness-Testimony-Policy-04.07.15-Revised-2013.pdf> Recommended agreement provision regarding University/private separation:  
<http://otm.wustl.edu/forfaculty/consultingagreements.asp> [cannot locate]
- WU Intellectual Property Policy: <http://www.wustl.edu/policies/intelprop.html>
- OTM Guidance on consulting agreements:  
<http://otm.wustl.edu/forfaculty/consultingagreements.asp>