UW Medicine Policy for Faculty on Potential Financial Conflicts of Interest with Commercial or Non-profit Entities

I. Purpose

It is the policy of UW Medicine that School of Medicine (SOM) faculty avoid or disclose and address perceived or real conflicts of interest between their responsibilities as faculty of the SOM and their activities with outside commercial or non-profit entities. This policy will guide SOM faculty in their interaction with these entities so that they may continue to contribute to the mission of UW Medicine in a manner that ensures the faculty avoid real or perceived conflicts of interest. There are five core concepts upon which this policy is based: (1) disclosure; (2) a general prohibition on gifts; (3) the requirement that outside compensation be at fair market value; (4) the requirement for pre-approval of outside compensation; and (5) the avoidance of the appearance of conflict, as well as actual conflict.

This policy applies to the following faculty of the School of Medicine: acting, regular, research and clinical faculty (except that it does not apply to clinical faculty who are not paid by the SOM, University of Washington Physicians (UWP), Children's University Medical Group (CUMG), or an SOM affiliate) and teaching associates ("SOM faculty" for purposes of this document). It applies to these individuals regardless of institutional affiliation or institutional site. This policy applies to activities whether they occur on the UW campus or elsewhere. We encourage all faculty not otherwise covered above to be aware of this policy and follow the intent and guidelines of the policy.

UW Medicine encourages appropriate relationships between SOM faculty and industry and non-profit organizations in so far as those relationships advance the mission of UW Medicine and help UW Medicine fulfill its community obligations. The purpose of this policy is to discourage interactions and relationships with commercial or non-profit entities if those interactions and relationships would align the faculty member toward the goals of a commercial or non-profit entity *and* away from the mission of UW Medicine, its students and/or its patients. This policy is not meant to discourage collaboration with commercial or non-profit entities if those interactions have the safeguards outlined below in this policy. This policy also is informed by the emerging national consensus on potential conflict of interest and the emerging research on the important role played by unconscious influences as well. See The Scientific Basis of Influence and Reciprocity: A Symposium, June 12, 2007 (http://www.aamc.org/reciprocity).

A significant component of this policy is disclosure of potential conflicts of interest, including disclosure of outside compensation. While disclosure alone is not sufficient to address all potential conflicts, the purpose of this disclosure is to enable faculty and leadership to avoid situations in which these potential conflicts may adversely affect the

¹ "Affiliate" for purposes of the applicability of this policy includes Seattle Children's Hospital ("Seattle Children's"), the Fred Hutchinson Cancer Research Center ("FHCRC"), the Veteran's Administration ("VA"), the Puget Sound Blood Center, and the Howard Hughes Medical Institute.

patients, research subjects, students, trainees, or employees of UW Medicine. This policy also imposes limitations on the relationship between outside commercial and non-profit entities and SOM faculty in the areas of support for educational events, gifts, and travel or meetings funded by outside commercial or non-profit entities.

There are a number of existing policies and procedures of the University of Washington, UW Medicine and affiliated institutions that apply to activities in this area. The purpose of this policy is not to replace those existing requirements, but rather to supplement and refine them to deal with the academic, clinical, research, and regulatory environment of the SOM. To the extent these existing policies and procedures provide less stringent requirements to protect against conflicts of interest, the more stringent requirements of this policy shall apply. These existing policy and procedures include (but are not limited to):

- 1) Washington State Ethics in Public Service Act, RCW Chapter 42.52 http://apps.leg.wa.gov/RCW/default.aspx?cite=42.52
- 2) University Policy on Employee Conflict of Interest, University Handbook, Volume 4, Part 5, Chapter 2 http://www.washington.edu/faculty/facsenate/handbook/04-05-02.html
- 3) University Significant Financial Interest Disclosure Policy, Grants Information Memorandum 10 http://www.washington.edu/research/osp/gim/gim10.html
- 4) University Outside Professional Work Policy (Academic Personnel), University Handbook, Volume 4, Part 5, Chapter 6 http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html
- 5) Annual Report of Outside Activities http://www.washington.edu/admin/acadpers/faculty/annual report system.html
- 6) University Statement on Employee Responsibilities, University Handbook, Volume 4, Part 5, Chapter 1
 http://www.washington.edu/faculty/facsenate/handbook/04-05-01.html
- 7) University Patent, Invention, and Copyright Policy, University Handbook, Volume 4, Part 5, Chapter 7 http://www.washington.edu/faculty/facsenate/handbook/04-05-07.html
- 8) ACCME Standards for Commercial Support

 http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c uploaddocument.pdf

- 9) UW SOM Ghost Authorship Policy http://depts.washington.edu/clinres/pdfs/SOMGhostAuthorshipPolicy2007.pdf
- 10) UW SOM Graduate Medical Education Vendor Interaction Policy http://uwmedicine.washington.edu/Education/ResidenciesAndFellowships/Policies/GME+Vendor+Interaction+Policy.htm
- 11) UW Medical Center Policy on Representatives, Health Care Industry, in the Operating Room (the following link is password protected)
 https://departments.medical.washington.edu/uwmcpcs/deptpnp/SurgicalServices/Report.htm
- 12) UW Medical Center Ethics, Standards, and Compliance http://uwmedicine.washington.edu/NR/rdonlyres/4F3D405C-CDE3-45B8-9111-CB71EB2BFA89/0/IntegrityAtWorkMay2007.pdf
- 13) HMC Policies on Vendors in Clinical Areas, Drug and Device Purchasing and Purchasing of Implant and Investigational Devices (the following link is password protected)

 https://hmcweb.washington.edu/NR/rdonlyres/1456DC6A-739D-4D88-80B4-E202750DFF81/0/Pol8018MDstaff.pdf
- 14) Harborview Medical Center Ethics, Compliance Standards and Code of Conduct http://uwmedicine.washington.edu/NR/rdonlyres/0041D53B-4317-4518-A6EA-A3238B3E669B/0/IntegrityAWork_Nov06.pdf
- 15) Seattle Children's Hospital Policies (all sites require Children's logon privileges) on:
 - a. Conflicts of Interest and Fiduciary Duties of Trustees and Managers (applies to medical staff with leadership responsibilities)
 http://child/policies procedures/administrative/conflicts of interest and fiduciary duties of trustees and managers.asp
 - Vendor at Educational Events
 http://child/policies_procedures/administrative/vendor_at_educational_events.
 - c. Vendor Presence http://child/policies_procedures/administrative/vendor_presence_on_premises_asp
 - d. Vendor Solicitation http://child/policies procedures/administrative/vendor solicitation.asp
- 16) Fred Hutchinson Cancer Research Center Policies
 - a. Conflict of Interest Policy http://extranet.fhcrc.org/EN/sections/general_counsel/policies/conflict_interest_20.pdf
 - b. Policy and Guidelines for Involvement with Outside Interests http://extranet.fhcrc.org/EN/sections/general_counsel/policies/outside_interests.pdf

II. Prohibited or Allowable Compensation/Relationships with Commercial or Nonprofit Entities

A. Gifts

Washington State law and the University's existing Conflict of Interest Policy impose significant limitations on the ability of UW SOM faculty members to accept or receive gifts. A gift is considered anything of economic value given to the faculty member for which the faculty member does not provide a service or other value in return. Gifts do not include such things as presents from family members of the faculty, gifts exchanged among co-workers, and certain other limited exceptions. (RCW 42.52.010, http://apps.leg.wa.gov/RCW/default.aspx?cite=42.52.010)

For example, UW faculty may not receive, accept, take, seek, or solicit, directly or indirectly, anything of economic value as a gift, gratuity, or favor from a person if it could be reasonably expected that the gift, gratuity, or favor would influence the vote, action, or judgment of the officer or employee, or be considered as part of a reward for action or inaction. (RCW 42.52.140, http://apps.leg.wa.gov/RCW/default.aspx?cite=42.52.140)

In addition, as a general rule no UW faculty may accept gifts in connection with their activities and responsibilities as faculty where the value of any gifts received from any one entity, individual or group of related individuals exceeds fifty dollars in any fiscal year. Faculty members who are involved in the acquisition of goods or services may not, with limited exceptions, accept any gifts regardless of dollar value from those who seek to provide the goods or services to the University (RCW 42.52.150, http://apps.leg.wa.gov/RCW/default.aspx?cite=42.52.150). Gifts received from patients can be accepted but these gifts are governed by the foregoing limitations and exclusions.

Gifts in excess of fifty dollars in value and/or gifts related to the faculty members' University work may be accepted by the University or an affiliate consistent with the policies and procedures of the institution on accepting and administering gifts. For the University of Washington, see:

University Handbook Volume 4
http://www.washington.edu/faculty/facsenate/handbook/Volume4.html,
Grants Information Memorandum 34
http://www.washington.edu/research/osp/gim/gim34.html and
Gift Processing Guidelines
https://devar.washington.edu/departments/gpa/AdminPolicy.asp

Even though Washington State law and University policy do not prohibit all gifts as described above, it is the policy of UW Medicine to prohibit SOM faculty from accepting any form of personal gift from commercial entities and non-profit entities created and supported by commercial entities, or their representatives, including promotional items such as pens or pads, pharmaceutical samples for personal and family use, entertainment or recreational opportunities, cash or cash equivalents, and business courtesies such as food and beverages.

B. Food and Beverages

It is the policy of UW Medicine that food and beverages provided by commercial entities or non-profit entities created and supported by commercial entities are not permitted at UW Medicine operated facilities (including UWMC, HMC, the SOM, and South Lake Union) or at off-campus events held by UW Medicine, any of its component entities, or any of its faculty.

In off-campus events not sponsored by UW Medicine, its component entities, or its faculty, there are certain limited circumstances in which faculty, including those responsible for the acquisition of goods and services, are allowed to accept and consume food and beverages provided by others. In general, faculty may accept food or beverages that are incidentally provided at an event that is considered part of the job duties of the faculty member. Food and beverages may be accepted and consumed at events sponsored by civic, charitable, specialty or job-related professional organizations, governmental, or community organizations. In other situations, faculty members should refrain from accepting gifts of food and beverages from commercial or non-profit entities created and supported by commercial entities.

C. Consulting With Commercial or Non-profit Entities

Consulting is appropriate where faculty provide real value and receive reasonable compensation. It is the policy of UW Medicine that a faculty member should accept only fair market compensation for specific, legitimate services provided by him or her to the commercial or non-profit entity in question. Payment should be commensurate with the amount of time and effort spent on these activities. The terms of the arrangements, services provided and compensation should be set forth in writing. In addition, the faculty member must follow the University Outside Professional Work Policy (see below). If there are questions, faculty members are encouraged to consult with their immediate departmental supervisor (i.e. chair, division chief or service chief), department director or administrator, and/or hospital medical director.²

D. Speeches, Meetings, and Travel Funded by Commercial or Non-profit Entities

Under the University's existing Outside Professional Work Policy, faculty are encouraged to participate in the work of non-profit professional associations and societies, to contribute their expertise to scholarly, editorial, and advisory bodies, and to serve on public commissions or boards of philanthropic organizations. Faculty are also encouraged to accept invitations by non-profit organizations, colleges and universities, and governmental agencies for purposes of presenting guest lectures, delivering papers, serving on review panels, and participating on accreditation activities.

² There are additional laws and regulations that apply to arrangements involving health care related entities. Faculty should be aware of these laws and restrictions, and should consult with their own personal advisors as appropriate whenever this type of consulting is occurring.

These involvements are characterized as University and community service, not as outside consulting, and prior approval is not required (provided, if they involve time away from the University, approval for travel away from the University should be sought from the appropriate supervisor). Such activities should be reported annually using the Annual Report of Outside Activities (see below). This exclusion does not apply to teaching credit courses or participating in continuing education activities not under the aegis of the University; prior approval for such activities must be sought.

In such instances of University and community service, it is not uncommon for a faculty member to receive some form of honoraria (money or a thing of value) for such activities. Under existing University policy, faculty are specifically authorized to accept honoraria for these activities, except that faculty are not permitted to accept honoraria in situations where the person, company, or organization offering the honoraria wants to sell goods or services to the University, and the SOM faculty member is in a position to influence the University's decision to acquire that type of good or service. (University of Washington Handbook, Volume Four, Part V, Chapter 6, Section 7,

http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html#anchor7.)

When compensation, including payment for travel and lodging, is offered to a faculty member by a commercial entity or a non-profit entity for a speech, appearance, article or similar activity that is not part of the faculty member's University work, the compensation may still be accepted, provided the payment is commensurate with time and effort as described above under Section C. dealing with consultation and provided that advance permission for the work is obtained pursuant to the University Outside Professional Work Policy.

In addition to the foregoing, it is the policy of UW Medicine that faculty who simply attend a CME or other instructional activity and are not organizing or presenting at the meeting should not accept compensation from companies either for attending or defraying costs related to attending the meeting. Similarly, SOM faculty should not accept compensation for simply listening to a sales pitch (e.g., detailing) by an industry representative.

E. Accepting Positions on the Boards of Commercial or Non-profit Entities

When faculty members consider accepting a position on the board of an outside commercial or non-profit entity, they should consult the relevant University Handbook policy found at: Volume Four, Part V, Chapter 6: Outside Professional Work Policy (http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html). Section 6 of this chapter, entitled "Involvement with Commercial Enterprise, Deeper than Consulting," provides guidance for faculty on accepting board positions.

III. Disclosure of Compensation/Relationships with Commercial or Non-profit Entities

A. Disclosure of Outside Compensation or Faculty Support

Which relationships require disclosure?

All faculty relationships with commercial and non-profit entities require disclosure in advance, or as part of an annual reporting obligation, or both. Disclosure is required by faculty members when they receive remuneration from a company for outside work or for inventions or discoveries made as a University employee (stock ownership, stock options, equity interests, stock warrants, royalties, consulting fees, loans from the sponsor, speaking arrangements), or hold office in or serve on the board of a company (board of directors, scientific advisory board, other office in the company) – see process for disclosure (below) for details on how to report. Faculty are encouraged to inform their division head and department chair if they are in a negotiation phase in order to receive guidance about the appropriateness of the relationship and compensation.

Annually, faculty will also need to disclose support from outside commercial and non-profit entities received by the institution for the use or benefit of the faculty. Examples include grants, endowments, equipment, materials, discretionary funds, support of office or research staff, sponsorship of trips, or other sponsorships – see process for disclosure (below) for details on how to report.

Which relationships do not require disclosure?

Excluded from this disclosure policy are institutional or departmental financial arrangements in which the faculty member does not control the funds.

Relationships with governmental and academic entities do not require disclosure of compensation amounts, however the UW does require other information in the Annual Report of Outside Activities (organization name and type, type of activity, description of activity and days spent) – see process for disclosure (below) for details on how to report.

Process for disclosure

Disclosure will be provided through the following mechanisms:

Professional Work Policy, faculty must obtain advance approval to engage in outside activities for remuneration. Faculty do so by completing a Request for Approval of Outside Professional Work for Compensation Form. As described above, certain activities involving certain non-profit organizations, colleges and universities, and governmental agencies are more appropriately characterized as University and community service, rather than as outside consulting, and do not require prior approval; provided, if they involve time away from the University, approval for travel away from the University should be sought from the appropriate supervisor.

(http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html)

- a. It is the policy of UW Medicine that, if the outside work requiring prior approval includes compensation that has monetary value, the faculty must submit on a form to be developed by the Dean the estimated or proposed contracted monetary value of all compensation. The form will show the monetary value of payments, the organization providing the payment, and an indication of whether other compensation (travel, destination, lodging, etc.) was also provided. The value of these other items need not be reported.
- b. The request for approval of outside professional work will be reviewed within the SOM, in accordance with the existing outside work approval process, for conformance with the fair market value requirement. The School will establish an appropriate internal review process for situations in which there is an initial determination that the fair market value standard is not met.
- 2) Annual Reporting. Under the existing University Outside Work Policy, faculty must also submit a summary of all outside professional work, both for remuneration and for public and community service, for the previous academic year by November 15 of each year. Faculty do so by completing the Annual Report of Outside Activities (http://www.washington.edu/admin/acadpers/faculty/annual_report_system.html).
 - a. It is the policy of UW Medicine that faculty will be required to provide on the Annual Report form, or on another form determined by the Dean, the monetary value of the payments actually received, and an indication of whether other compensation (travel, lodging, etc.) was also received although the value of these other items need not be reported.
 - b. It is also the policy of UW Medicine that faculty will report at the end of the year, on the same or similar form, a list of all outside commercial or non-profit entities from whom a faculty member received grant support or other similar support (see Section 1.a above). This will be reported in a manner similar to that which is required by journals for disclosure of grant funding that could pose a conflict of interest.

How will disclosure information be distributed?

Information that normally flows to the Provost's office will continue to do so. nitially, the additional COI disclosure information (including compensation levels) will be distributed to relevant leadership in UW Medicine, including: the Dean of the SOM, department chairs, division heads, hospital medical directors, and hospital executive directors.

At such time as a UW Medicine website with appropriate information and links related to this topic is developed, it is anticipated that this additional disclosure information will be placed there. Access will require a UW Net ID. Faculty should also be aware that this information is considered in the public domain and could be requested by individuals or organizations outside of the University of Washington.

B. Disclosure of Potential Conflicts When Faculty are Involved in Teaching Activities

When involved in teaching activities (including lectures to medical students and residents, seminars, conferences, and community service activities with a teaching component), faculty must directly disclose to the audience relevant potential financial conflicts. Disclosure of potential financial conflicts in connection with teaching activities should include both the relationships required to be disclosed in Part II above (i.e., outside compensation) as well as institutional gifts, grants, or other financial support from a commercial or non-profit entity to support the faculty member's University work. Dissemination may be performed through written materials distributed prior to or at the presentations or classes, at the time of presentation through disclosure slides preceding the content of the presentation, or by a verbal statement at the beginning of the presentation. Compliance with these standards is required regardless of whether formal CME credit is awarded or not.

Outside Support for Educational Events

Faculty who participate in or plan educational activities should be aware that industry support for educational activities within UW Medicine institutions or UW Medicine educational program in any location is permitted only if <u>all</u> of the following conditions are met:

- a. The support is unrestricted with respect to content, topic, and speaker;
- b. The support is limited to payment for the direct costs of the educational activity;
- c. The support is made at a divisional or departmental level for general educational purposes and not for individual faculty members;
- d. Industry may NOT designate particular individuals as the recipients of support for travel, accommodations, books, subscriptions, meeting registration, etc.;
- e. Industry representatives may attend but not participate in the educational event or participate in the event as an opportunity to market products;
- f. Support is in compliance with all applicable Accreditation Council for Graduate Medical Education (ACGME)/Accreditation Council for Continuing Medical Education (ACCME) standards; and
- g. No trinkets, gifts, promotional material, free samples, or other marketing materials are available at the educational event. Only educational materials may be distributed at an educational event.

Vendors or manufacturers providing support for an educational event may be acknowledged and thanked for their support in an appropriate fashion, such as verbally at the event, website acknowledgement, a simple sign, or in the written program.

ACCME standards can be found at the ACCME website (http://www.accme.org/) and relate to interactions with industry in terms of independence of program planning, resolution of conflicts of interest, appropriate use of commercial support, management of commercial promotion, and handling potential content bias.

C. Disclosure and Hospital Policies on Vendor Relations

Faculty with clinical responsibilities should also become familiar with policies on vendor relations and integrity at work policies for the clinical setting in which they practice. Institutional policies may have additional requirements that apply to vendor relationships. The hospital medical director should be consulted for applicable policies. In general, vendors will not be allowed in clinical areas unless their presence is required by the practitioner for the care of a patient and the presence is completely independent of any decision to purchase or utilize a product.

Faculty must disclose any conflicts of interest, including both the relationships required to be disclosed in Section II above (i.e., outside compensation) as well as institutional gifts, grants, or other financial support from a commercial or non-profit entity to support the faculty member's University work, if they are responsible for making purchasing decisions or advising others on decisions to purchase or lease health care devices, pharmaceuticals, implants or other expenditures. Such faculty must also recuse themselves from any final decisions regarding purchase of goods or services that such vendors supply.

IV. Whom to Contact for Further Guidance:

When faculty have questions about their relationships with outside health care entities, they should consult their immediate departmental supervisor (i.e. chair, division chief, or service chief), department director or administrator, and/or hospital medical director.

V. Policy Implementation and Review:

The policy will be reviewed annually and updated as appropriate. All faculty members of the UW SOM should review this policy on adoption, on joining the faculty and following any updates. Chairs and division heads are to work with their faculty to assure compliance with the requirements of this policy.

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