UW Medicine

UW Medicine Guidance Document For Receipt of External Support/Gifts by Vendors

A. Statement of Purpose

This document provides guidance for UW Medicine entities related to their acceptance of vendor support/gifts.¹

B. Scope

This guidance applies to all entities in UW Medicine.

C. Definitions

- 1. Acknowledgment: term used to signify the recognition of sponsorship support. Typical acknowledgment may include logo placement and/or sponsor information in the materials associated with a UW Medicine event or activity being supported by the sponsor.
- 2. Benefit: any item or service provided to a sponsor in return for the sponsorship of a UW Medicine activity, event, or program. Examples include, but are not limited to, acknowledgment, event tickets, food and beverages, merchandise, or access to UW Medicine services (i.e., meeting rooms, job boards, etc.).
- 3. External Support: anything of economic value provided by a third party (either the "sponsor" in the case of sponsored projects or sponsorship arrangements, or the "donor" in the case of gifts) for use in a project or other activity conducted by or at a UW Medicine entity.
- **4. Gift:** the voluntary provision or contribution of external support without any expectation of economic or tangible benefit in return. The contributor of the gift is called a "donor" and the donor's intent must be philanthropic or charitable. No goods, services or deliverables are offered to the donor for receipt of the contribution; it is not earned by the receiver. Gifts and donors may be publicly recognized by UW Medicine. Gifts may be designated for a special purpose or unrestricted by the donor. Valid restrictions pertain to the permitted use of gift funds rather than providing a result to the donor. <u>See University of Washington Grants Information Memorandum 34 on the Classification of External Support (GIM 34).</u>
- 5. In-Kind or Value In-Kind: a product or service provided by a sponsor in lieu of cash to UW Medicine, including a hospital, clinic, campus, school, college, department, unit, or student organization as part of a sponsorship agreement, a gift or a sponsored project.
- 6. Sponsored Project: any project (including research, scholarly work, training, workshop, and service) receiving external support that has defined performance requirements. The following conditions may apply: delivery of specific goods, services, or other deliverables by UW Medicine; performance milestones; transfer of intellectual property, ownership, or related

¹ The term UW Medicine is used throughout this document to refer to each UW Medicine entity either individually or collectively. The term University is used where specific reference to the University of Washington is appropriate.

- rights; insurance, indemnification, or warranty; restrictions on publication of research results; or audit requirements (See GIM 34).
- 7. **Sponsorship:** relationship with an entity where the entity provides money, goods, and/or services, and in return, the entity receives **acknowledgment** of the sponsorship via television or radio broadcasts, signage, tickets, programs, other print materials, or the internet.
- 8. Vendor: any business entity or individual that has, is, or could in the future sell goods or services to UW Medicine or any entity of UW Medicine. It includes but is not limited to businesses that manufacture or sell drugs or medical devices.

D. Regulatory Framework

UW Medicine operates in a complex federal, state, and entity specific regulatory and policy environment with regard to their interactions with vendors, especially with respect to the area of external support from vendors. Whether and under what conditions the acceptance of external sponsorship is appropriate must take into account and be compliant with the following regulatory frameworks:

- 1. Anti-Kickback Statute (AKS): A Federal Regulation that prohibits seeking, offering or accepting payment or other transfer of value in exchange for referring an individual for items or services covered by a federal healthcare program, or for purchasing (or recommending for purchase) an item or service that is reimbursable under federal healthcare programs. The AKS applies to everyone including physicians, non-physicians and other individuals and entities.
- 2. The Washington State Ethics Act: State law that prohibits any state officer or state employee to have a direct or indirect interest (financial or otherwise), engage in a business or transaction or professional activity, or incur an obligation of any nature that is in conflict with the proper discharge of the state officer's or state employee's official duties. It limits the receipt of gifts and extra compensation for official duties and prohibits the use of state resources for personal benefit or gain, or for the benefit or gain of another. (See RCW 42.52). This law does not apply to employees of Northwest Hospital (NWH) and Valley Medical Center (VMC) because they are not state employees. Both NWH and VMC have a Conflict of Interest policy with similar features and concepts.
- **3. GIM 34:** University guideline that describes its policies and standards for classifying external support as either a sponsored project or a gift, and the administrative procedures for accepting and processing external support. (See GIM 34)
- 4. University Sponsorship Policy, Executive Order (EO) 15: University presidential order designed to establish processes and provide guidance to all University campuses, schools, colleges, departments, academic or administrative units, student government, and other University organizations that engage in sponsorship recognition, including designation as a sponsor, trademark rights, events, programs, media and communications, or other activities. This policy does not pertain to gifts through University Advancement. (See EO 15)
- 5. Advertising by University Departments, EO 40: University presidential order governing the purchase or utilization of advertising by University departments. (See EO 40)

- **6.** University Trademark and Licensing Policies: University policies governing the use of University trademarks including the licensing thereof. (See University Trademark and Licensing Policies)
- 7. University Purchasing Policies and Procedures: Policies and procedures that help ensure the integrity of the procurement process, minimize the influence of vendor gifts on the procurement process, and address issues of conflict or potential conflict between vendors and University workforce members involved in the procurement process. These policies and procedures include hospital policies on the product evaluation process, conflict of interest, purchase of meals and light refreshments, and vendors on premises.
- 8. UW Medicine Policy for Faculty on Potential Financial Conflicts of Interest Policy (COI): A policy requiring UW School of Medicine (SOM) faculty to avoid, or disclose and address, perceived or real conflicts of interest between their responsibilities as faculty and their outside activities while at the same time encouraging appropriate relationships between faculty and industry to the extent that they further the mission of UW Medicine. (See COI Policy)
- 9. UW Advancement and UW Medicine Advancement (UWMA) Policies and Procedures: Relevant policies here include UWMA Guidance for Solicitation of Underwriting for Institutional/Departmental Educational Activities/Events. Note: all fundraising for gifts must be organized with and approved by UWMA.
- 10. UW Policy on Naming Spaces: Any gifts related to a naming opportunity in any UW interior or exterior space is subject to UW Board of Regents Policy No. 6. (See Regent Policy No. 6)

E. Key Guidance Provisions

From a regulatory or compliance standpoint, unrestricted gifts of money from donors who do not sell or market products, items or services to the University or UW Medicine pose the least amount of risk. These gifts can be processed routinely by Advancement subject to the documentation requirements in section F. below. Gifts from commercial entities, industry and vendors may raise various concerns based on the following factors: the type of restrictions on the gift; the benefits received by the donor or any performance required by UW Medicine in return for the gift; the nature and status of the vendor making the gift; the status of the UW Medicine representative seeking or primarily benefitting from the gift; the type of item received (other than money); and whether the gift is connected to research activities. These gifts should receive additional review as set forth below:

1. Restricted Gifts

- a. <u>Educational Fellowship</u>—the donor may restrict the topic but may not dictate the focus or point of view. The donor also may not choose the recipient of the fellowship, limit the duration of time to spend the gift or request the return of unspent funds.
- b. <u>Educational Conference</u>—any gifts to support scientific and educational activities should comply with the UW Medicine COI Policy, the FDA Guidance for Industry on Industry-Supported Scientific and Educational Activities, the ACCME Standards for Commercial Support and the UWMA Guidance for Solicitation of Underwriting for Institutional/Departmental Educational Activities/Events. These guidelines require, inter

alia, that UW Medicine retain full control over the program's content and over the selection of speakers; that the company's funding of the program be fully disclosed; that no company representative be a presenter; that no company's promotional activities take place in connection with the activity with the exception of providing approved educational materials; and that solicitations are not limited to the department's vendors and go beyond medical device and pharmaceutical companies. Note: funding to support accredited CME activities are processed by the UW SOM CME office and are treated as CME program revenue.

- c. Vendor Training/Travel Reimbursement—the purpose of the training must be training/educational. Money must come to the institution and the institution must be able to select the individuals who will attend. If the purpose of the event is to promote a product, the gift must be refused and traveling to a vendor site to see a product demonstration must be done as part of the purchasing process/due diligence and paid for by UW Medicine.
- d. <u>Endowments</u>—endowments that contain the name of the company are acceptable provided the endowment agreement does not contain any language that would imply the company has a role in choosing who receives the funding; and provided that spending authority is clearly outlined in the endowment agreements and cannot be changed without an amendment to the agreement.
- e. <u>Named spaces</u>—any gifts related to a naming opportunity in any University interior or exterior space is subject to UW Regent Policy No. 6. (<u>See Regent Policy No. 6</u>)

2. Benefits Received or Performance Required

- a. Benefits—External support arrangements in which the vendor seeks any item or service from the University or UW Medicine in return for the support (other than public recognition by the University or UW Medicine of donors through accepted University underwriting guidelines) must comply with the University Sponsorship Policy, EO 15. In addition, any benefit(s) received must be consistent with the nature of the donation as a gift and the provision of any benefit is at the discretion of UWMA. Areas of attention include protecting the University's and UW Medicine's reputation and image in the choice of sponsors; appropriately balancing the value to the sponsor for associating with the University and/or UW Medicine against the value to the University and/or UW Medicine of the external support; and protection of University and UW Medicine trademarks, names, or logos.
- b. <u>Grant</u>—If the external support (including research, scholarly work, training, workshops, and services) has defined performance requirements such as delivery of specific goods, services, or other deliverables by UW Medicine, performance milestones, transfer of intellectual property, ownership, or related rights; insurance, indemnification, or warranty; restrictions on publication of research results; or audit requirements, the external support should be reviewed against GIM 34 to determine if should be more accurately characterized and processed as a grant by the Office of Sponsored Programs (OSP) under GIM 34.

3. Nature and Status of the Vendor

- a. <u>Drug or Device Manufacturer</u>—Drug or device manufacturers present special challenges due to the AKS. All gifts from drug, device and equipment companies or manufacturers must be scrutinized to ensure that gifts are not being made or accepted to induce or reward the referral or generation of federal health care business or in return for purchasing, leasing, or ordering any item or service reimbursable by a federal healthcare program.
- b. <u>Current or Prospective Vendor</u>—Gifts from current or prospective vendors must be reviewed to ensure that the gift is not a quid pro quo for the current contract or for award of future contracts.

4. Status of UW Medicine Employee Seeking or Benefitting from Gift

Special scrutiny should be given where the faculty or staff person who is seeking the gift or who may receive a professional benefit from the gift (such as a gift of lab equipment to a researcher) is in a position to generate federal healthcare business. This includes physicians, allied healthcare professionals, formulary committee members, or purchasing agents.

5. Type of Item Received (Non-Cash gift)

- a. <u>Pharmaceuticals</u>—Vendor gifts of pharmaceuticals require review with UW Medicine Pharmacy leadership.
- b. <u>Medical Equipment and Devices</u>—Vendor gifts of medical equipment and devices for clinical use are typically never permitted. Instead, transfer of equipment or devices should be done at fair market value pursuant to contract or agreement rather than as a gift. Gifts of equipment and devices for education or research purposes are often permissible but are all subject to review by UWMA.
- c. Non-Medical Equipment—Same as 5.b. above.
- d. <u>Computers or Software</u>—Particular concerns related to computers and software include the risk that acceptance of a gift of computers or software may "lock in" the entity to future purchases of the same vendor's product.
- e. <u>Supplies and Discounts</u>—These gifts need to be evaluated carefully with the relevant purchasing departments. Such gifts can be appropriate if structured correctly.
- f. Food and Beverage—Vendor gifts of food and beverage are not permitted under the UW Medicine COI Policy in any UW Medicine facility or at any event sponsored by UW Medicine. As an alternative, the vendor may make an unrestricted gift to the relevant UW Medicine entity/unit.
- g. <u>Services or Time</u>—Vendor gifts of services or time require special attention to distinguish appropriate volunteer support from situations involving an expectation of future consideration. These types of activities do not qualify as charitable gifts per IRS regulations and the donor will not receive a gift receipt.

6. Research Relationship

Gifts in support of specific ongoing research raise additional issues primarily related to potential researcher conflict of interest, and may also raise other federal compliance issues. Any gift to support on-going research should be reviewed by OSP.

F. Protocol for Processing, Approving, and Documenting External Support From Vendors

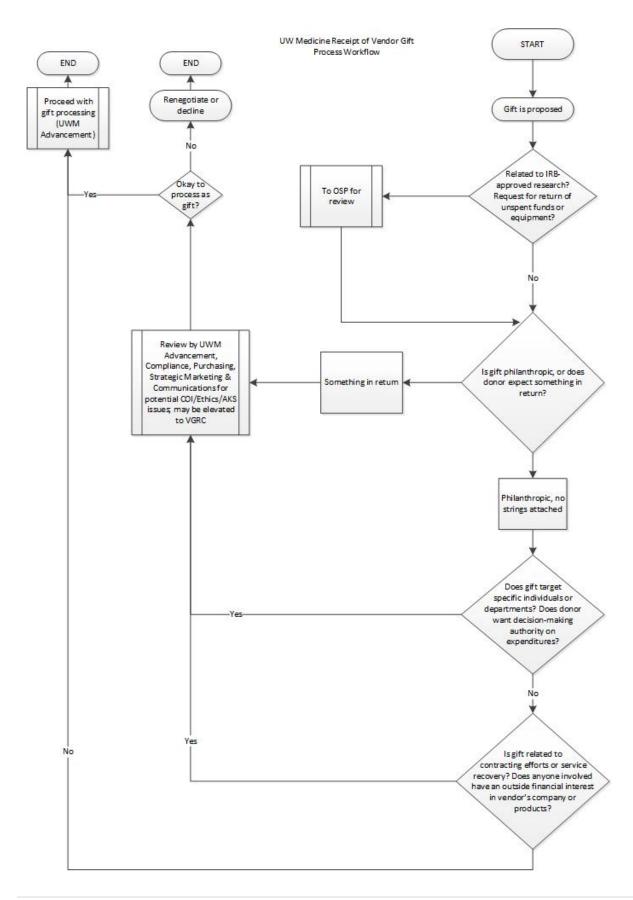
Approval for all gifts covered by this guidance will be required to follow the process identified in this guidance.

- Multiple Intake Points: The initial contact points for either soliciting or receiving vendor gifts
 or other offers of support can occur throughout UW Medicine, including in the clinical
 entities, in the School of Medicine, or in UW Medicine Advancement (UWMA). Regardless of
 the initial contact point, UWMA should be brought into the discussions with the vendor at the
 earliest opportunity.
- 2. UWMA Will Lead Review Process: At the point UWMA is brought into the discussion, they will be on point for ensuring the guidance set forth in this document is followed determining whether to accept the vendor gift or support. Unrestricted gifts that come from non-pharma entities should be processed by UWMA in the normal course of business. For restricted gifts, gifts from current vendors, gifts from pharma, gifts that involve the provision of University benefits in return (sponsorships), or in any other non-routine gift situation, UWMA will engage in a deeper review as described below.
- 3. Deeper Review: As part of its deeper review, UWMA will fill out the checklist attached to this guidance. The purpose of the checklist is to identify any issues of concern with the acceptance of the gift. UWMA will seek guidance as appropriate from UW Medicine Compliance, SOM Dean's Office Business Unit, the AGO, and respective clinical entity purchasing departments. Following its deeper review, UWMA will have the authority/discretion to accept, reject or renegotiate the vendor gift/offer of support.
- 4. Vendor Gift Review Committee: In those cases where, after the deeper review described above, UWMA has continuing concerns over whether to accept or reject the gift, UWMA shall review the vendor proposal, along with the checklist, with the Vendor Gift Review Committee (VGRC). The VGRC will be a standing committee consisting of one or more representatives chosen by the UW Medicine Chief Health System Officer, Chief Financial Officer, Chief Business Officer, and Chief Advancement Officer. The VGRC shall have the authority to make a final decision on acceptance of the vendor gift or other offer of support.
- 5. Documentation: All vendor gifts and other offers of vendor support that are accepted shall be documented in a letter to the vendor from UWMA. UWMA will work with the donor and recipient to prepare the letter of acceptance. A sample of such a letter is attached to this guidance. A copy of the letter of acceptance shall be provided to other interested UW Medicine entities and individuals, including the institutional entity for whose benefit the gift is given, the clinical entity purchasing departments, UW Medicine Compliance, SOM Dean's Office Business Unit and UW offices (e.g., OSP) as appropriate.
- **6. Tracking Log:** In addition to documentation, all vendor gifts and other offers of support that are accepted will be entered into a tracking log created for this purpose. UWMA shall be

responsible for creating and maintaining the tracking log, and for entering each vendor gift accepted/received into the log.

G. Attachments

- 1. Vendor Gift Processing Work Flow Chart
- 2. Receipt of Vendor Gifts Checklist
- 3. Sample Vendor Gift Letter of Agreement



UW Medicine

Receipt of Vendor Gifts Checklist

ID:

Start Date:

Name of Donor:

Type of Donor:

Amount:	Department/Division/Hospital:			
	Yes	No	Notes	
Is the gift monetary?				
Is the gift non-monetary? I.e. goods, services, equipment, supplied	es,			
airfare, accommodations, or other in-kind types of gifts?				
Describe the gift:				
Was gift proposed by vendor?				
If no, who initiated gift conversation:				
Is this related to any IRB-approved research projects?				
If research-related, has OSP reviewed the proposed gift?				
Are there any stipulations regarding return of unspent funds or				
equipment?				
Is gift philanthropic/no-strings outside of normal stewardship?				
Does donor wish to have us do something for them—i.e. report r purchase other products or supplies from them, etc.?	esults,			
If yes, what does the donor want:				
Is gift targeting any individuals or departments?				
If yes, names of involved parties:				
Is donor requesting any kind of decision-making authority regard	ing			
how funds are spent?				
If yes, describe:				
Is gift related to any contracting efforts, either existing contracts	or			
contracts-in-negotiation?				
Is gift a "service recovery"?				
How will the gift be used within the UW? (select below and brief describe)	ly			
Clinical:				
Research:				
Academic:				
Other:				
Does anyone involved have an outside financial interest in vendo	r's			
company?				
If yes, names of involved parties:				
Notes:				
Resolution:				
Resolution Approval:		Date	o:	

UW Medicine

[Area] Gift Agreement

I. Agreement

The University of Washington and UW Medicine through [legal entity e.g. School of Medicine] ("the University"), an academic medicine institution located in Seattle, Washington, USA, and [donor name] ("the donor") [brief description of donor/type of company and location] hereby agree to the terms of this Gift Agreement, to become effective on such date as this Gift Agreement is executed.

II. Gift and Purpose

[Donor name] will make a gift of [amount] (the "Gift") to provide support for the [purpose, may include identification of program, fiscal administration and key faculty/administrative leaders] at the direction of the [title].

III. Recognition and Reporting

All major activities and accomplishments supported by the Gift shall appropriately recognize the generosity of [donor name]. UW Medicine will provide regular updates in a mutually agreed upon format to [donor name] regarding the impact of this gift on [project description].

IV. Gift Acceptance

The University is grateful for the generous gift from [donor name] and will accept the contribution subject to the University's standard gift acceptance conditions stated in Attachment A, incorporated herein.

V. Amendment

This Agreement may be amended or its term extended by the mutual written consent of the University and [donor name], as long as both are in existence.

VI. Integration Clause

This Agreement constitutes the entire agreement between the parties, and supersedes all prior oral or written agreements, commitments, or understandings concerning the matters provided for herein.

FOR THE DONOR:	FOR THE UNIVERSITY OF WASHINGTON:
[Name]	Paul G. Ramsey, M.D.
[Company]	CEO, UW Medicine
	Executive Vice President for Medical Affairs and
	Dean of the School of Medicine
	University of Washington
	[Director or Chair]
Date	Connie Kravas, Vice President
	University Advancement

Attachment A:

- 1) The University will expend the Gift solely for the purposes as stated in Section II. If any circumstances make the project or program being supported no longer feasible, or residual funds remain after the project is completed, the donor agrees to discuss with the University alternative options for expending funds.
- The University may publicly recognize the donor's generosity in publications or announcements promoting the Gift or the research supported by the Gift. Mention of UW Medicine's work and/or name is permitted in donor materials with the approval of UW Medicine Advancement. Use of UW Medicine- or University of Washington-related logos and/or wordmarks in the donor's materials is not permitted.
- The Gift is not intended as, nor does it represent, remuneration in exchange for referrals for health care services or items. The decision to offer this Gift to the University is not related to the volume or value of business generated by the University for the donor. The University, including its employees, officers, students, and agents, are not required or encouraged to use or purchase any product, equipment, or service manufactured or provided by the donor, or by any third party, as a condition of accepting the Gift.
- 4) The Gift is also not intended as, nor does it represent, remuneration in exchange for access to protected health information. This agreement does not authorize any sharing of protected health information.
- The Gift will be provided to the University of Washington. As a public institution, and in accordance with state law, the Gift may not be offered to any University of Washington employee, officer, student or agent for the individual's personal use or for a use by any other person or entity.
- 6) The Gift does not obligate the University to purchase the donor's products or products the donor suggests, equipment or services, or to provide preferential consideration in any matter, including the future purchase of products, equipment or services. In addition, the Gift does not imply endorsement or promotion of the donor's products or business.
- 7) If the Gift is used to support educational activities, the University will be solely responsible for the selection of the individual(s) to participate in these activities and program content.
- 8) The University may provide stewardship reports on progress but will not share detailed research results, intellectual property or detailed expenditure reports.
- 9) The University and donor intend this Gift Agreement to comply with all laws, regulations and requirements applicable to physicians, suppliers, and healthcare providers in general. This Gift Agreement shall be construed in a manner consistent with compliance with such statutes and regulations.