

CE-20 – Physician Interactions with Outside Sources¹

Key Points

- This policy applies to University Hospitals, all UH facilities, and all of its wholly-owned entities, including University Hospitals Medical Group (“UHMG”) and University Hospitals Medical Practice (“UHMP”) (collectively “UH”). This policy also applies to all UH-employed residents and physicians contracted in any capacity and/or affiliated physicians on any UH medical staff (collectively “Physicians”).
- UH encourages Physicians to participate in research and other educational activities that may involve relationships with Outside Sources. At the same time, UH recognizes that these relationships carry with them a potential for perceived or actual Conflicts of Interest.²
- On an annual basis, Physicians complete a Conflicts of Interest Disclosure Questionnaire and Statement (“Disclosure Statement”) to disclose Financial Interests³ and participation in certain outside activities that could be a Conflict of Interest. Additionally, Physicians update their Disclosure Statement within 30 days of a change in or termination of a Financial Interest or outside activity.
- Business arrangements involving Physicians and Outside Sources comply with this policy and, in certain circumstances explained in this policy, require advance approval.

Policy & Procedure

1. Principles.

- 1.1 UH encourages Physicians to participate in research and other educational activities that may involve relationships with Outside Sources. At the same time, UH recognizes that these relationships carry with them a potential for perceived or actual Conflicts of Interest.
- 1.2 UH requires Physicians to obtain advance approval for, and annually disclose, certain Financial Interests and relationships with Outside Sources so that an impartial decision-maker can assess whether a situation involves an actual or potential Conflict of Interest.
- 1.3 Not every Physician Financial Interest or relationship with an Outside Source is a Conflict of Interest.
- 1.4 Physicians may provide consulting services or pursue other activities outside their role at UH, as long as the activity is performed in compliance with applicable laws, UH policies and agreements.

- 1.5 UH resolves and manages Physician Conflicts of Interest in an appropriate and reasonable manner, which may include a management plan.
- 1.6 A Physician's failure to fully disclose a potential Conflict of Interest may render void any obligation of a UH entity in regard to a business transaction or arrangement affected by the conflict.
- 1.7 Violations of this policy by a Physician may result in corrective action up to and including termination.

2. Approval for Participation in Outside Activities.

2.1 Prior to engaging in certain outside activities, as outlined in this Policy, Physicians receive approval to participate in the activity. Outside activities that require advance approval prior to engagement are as follows:

- 2.1.1 **Salary or Other Payment.** Physician's receipt of Remuneration⁴ from an Outside Source that will exceed \$1,000 from that Outside Source within a 12 month period.
- 2.1.2 **Officer, Director, Trustee, or Policy Manager.** Physician or a Physician's Family Member's⁵ participation as a Director, Officer, Trustee, or Policy Manager for an Outside Source regardless of whether Physician or Physician's Family Member receives Remuneration for participation.
- 2.1.3 **Ownership Interest.** Physician or a Physician's Family Member's ownership in an Outside Source.
 - 2.1.3.1 **Publicly-traded entities.** With regard to a publicly-traded entity, Ownership means an ownership or equity interest through stock, stock options, or other ownership interests of 5% or more of the total outstanding equity of the company. Physicians with personal investments in a publicly-traded company recuse themselves from purchasing decisions involving the company's products or services. For Physicians who receive funding from the U.S. Department of Health and Human Services ("HHS") Public Health Service (including a grant, award or contract for federally-funded research from the National Institutes of Health), Ownership means the lower of (a) 5% or more of the total outstanding equity of the company; or (b) a level or ownership or equity interest that meets or exceeds the threshold established in HHS regulations.
 - 2.1.3.2 **Privately-held entities.** With regard to a privately-held entity, Ownership means any (no *de minimus* amount) ownership or equity interest.
 - 2.1.3.3 **Mutual funds.** Investments in mutual funds that are available to the public generally and have not been acquired as a result of a loan, gift, or other transfer of assets from an

Outside Source are not considered Ownership for purposes of this Policy.

2.1.3.4 **UH competitors.** Ownership interests in or other material financial relationships with a business or entity with which UH competes (e.g. health system, hospital, specialty hospital, ambulatory surgical center, diagnostic imaging center, healthcare insurer) are prohibited unless approved by the Executive Council of senior leadership (or designee).

2.1.4 **Intellectual Property.** Physician or a Physician's Family Member's interest in intellectual property that the Physician, Physician's Family Member or an Outside Source plans to commercialize from which the Physician or Physician's Family Member would benefit. Intellectual property interests include patents, copyrights, receipt of royalties, rights to receive royalties, and/or agreements to share in royalties related to such interests.

2.2 Requests for approval of participation in outside activities are submitted to the UH Office of Outside Interests using the "Request for Approval of Outside Interest" form at least 30 days prior to the effective date of the outside interest.

2.3 A Physician who provides services to an Outside Source has a written contract that details the specific duties and deliverables, with payment commensurate with the duties assigned and at fair market value. The Physician sends a copy of the proposed contract between the Physician and the Outside Source along with the "Request for Approval of Outside Interest" form.

2.4 Chair or President Approval.

2.4.1 Requests by UHMG Physicians are approved by the Physician's Department Chair. If the Chair has an inherent Conflict of Interest, the Physician's request is approved by the President of UH Case Medical Center. Requests by UHMG Chairs are approved by both the UHPS and UH Case Medical Center Presidents. Requests by UHMP Physicians are approved by the President of UHPS (or designee). Requests by Independent Physicians are approved by the Office of Outside Interests.

2.4.1.1 The Department Chair, President(s) and/or Office of Outside Interests may approve, approve with management plan, or not allow the Physician's request based on criteria listed in [Attachment A](#).

2.4.1.2 Requests for Ownership interests in an Outside Source are approved by the UH Physician Outside Interests Committee ("POIC") and reviewed by the UH Law Department.

2.4.1.3 Requests for approval of Intellectual Property interests from an Outside Source are approved by the UH Intellectual Property Officer, in accordance with UH Policy GM-21.

2.4.2 Criteria for Approval of Outside Activities.

2.4.2.1 A Physician's request for approval of a relationship with an Outside Source is evaluated on a variety of criteria outlined in [Attachment A](#).

2.4.2.2 A Physician's approval request is submitted along with a listing of the Physician's other outside activities by the Office of Outside Interests to the Physician's Department Chair or President(s) to facilitate the determination.

2.3 Law Department Review.

2.3.1 The UH Law Department reviews all contracts between a Physician and an Outside Source prior to execution of the contract.

2.3.1.1 Any legal review of a contract/request by the UH Law Department is to protect UH's interests and to confirm the agreement imposes no obligation on UH, involves no UH property or other UH resources, and is consistent with UH policies. The Law Department does not provide personal legal advice to any Physician. The Physician signing the agreement is encouraged to have the Physician's own attorney review the contract prior to execution of the agreement.

2.4 Notification of Decision Regarding Request for Approval of Outside Activities.

2.4.1 The Office of Outside Interests notifies a Physician of the decision regarding the Physician's approval request.

2.4.1.1 The Physician is notified of the decision with one of three outcomes: 1) approved; 2) approved with management plan; or 3) denied.

2.4.1.2 If approved, the Physician sends a copy of the executed contract to the Office of Outside Interests (instructions will be provided with the approval letter).

2.4.1.3 If approved and unless otherwise specified in a management plan, the Physician recuses himself/herself from all UH purchasing decisions involving the Outside Source's products or services, as well as all similar products from the Outside Source's competitors.

2.4.1.4 If approved with management plan, the Physician signs the management plan prior to executing the contract or beginning the outside activity.

2.4.1.5 If denied, the Physician may appeal the decision as described below in Section 2.6 of this Policy.

2.5 Management Plans. Approval of activities that involve a conflict of interest, with the individual or the institution are subject to a suitable management plan.

2.5.1 The management plan may include but is not limited to:

2.5.1.1 Requiring the individual to recuse him/herself from particular business activities;

2.5.1.2 Requiring the individual to inform certain persons or institutions (such as patients, journals, professional audiences) about the outside interest as proscribed by the management plan;

2.5.2 The Physician's Department Chair or President(s), the Office of Outside Interests or the POIC may determine that a management plan is necessary.

2.5.3 In determining whether a management plan is required, the Physician's Department Chair or President(s), the Office of Outside Interests or the POIC considers factors noted in Attachment A to this Policy. These factors include, but are not limited to, anticipated annual Remuneration and time commitment for this agreement and aggregate totals of all the Physician's agreements, when applicable. Additional factors include if intellectual property rights or ownership are involved.

2.5.4 If the Physician has a current management plan with Case Western Reserve University ("Case"), UH adopts this management plan and adds an addendum if necessary.

2.5.5 The Office of Outside Interests maintains the management plan for the duration of the agreement and sends a copy to the Department Chair or UHPS/UHCMC President, as applicable.

2.6 Appeal of Decision.

2.6.1 Physicians who have been denied approval of their request to participate in an outside activity may appeal the decision to the POIC.

2.6.2 The Physician's appeal should be in writing and sent to OutsideInterests@UHhospitals.org. The appeal should include compelling circumstances for why the Physician disagrees with the decision and reasons for why a reversal of the decision should be granted.

2.6.3 The Physician may be asked to appear before the POIC to present his/her case in person, and answer any questions the POIC may have for the Physician.

2.6.4 The POIC has the final authority to uphold or reverse a decision.

3. Outside Activities that Do Not Require Approval Prior to Engagement. The outside activities outlined in this Section do not require approval prior to engagement.

3.1 Receiving royalties from an Academic Institution⁶ for published scholarly work and other writings.

3.2 Receiving Remuneration of less than \$10,000 per occurrence from an Academic Institution for lectures, journal articles, educational tapes, visiting professorships, serving on grant review committees, or honoraria given by another academic institution for an academic activity, such as providing a seminar or grand rounds presentation.

3.3 Any activities specifically permitted by written contract with UH.

4 Reporting Disclosures.

4.1 On an annual basis Physicians complete a Disclosure Statement as directed by the Office of Outside Interests. If there has been no change in Physician's disclosure(s) from the previous year, Physician is only required to certify as such.

4.2 Physicians update their disclosure forms within 30 days of a change or termination of a Financial Interest.

4.3 Physicians submit an approval request form prior to engaging in any new activity that requires approval, as outlined in this Policy.

4.4 As part of the credentialing process and prior to granting privileges, the Medical Staff Credentialing Department from the respective UH facility verifies with the Office of Outside Interests that the physician has completed the Disclosure Statement.

5 Review of Disclosures.

5.1 Acting under the direction of the POIC, the Office of Outside Interests conducts an initial review of all disclosures. If necessary, the Office of Outside Interests obtains additional information from the Physician or other individuals who possess relevant information regarding the Physician's disclosure.

5.2 If the Physician conducts research as a faculty member of Case, UH works collaboratively with the Case Outside Interests Committee to review the reported activities and management plan(s).

5.3 In the case of a Physician who is newly hired at UH, the POIC may permit a prohibited conflict of interest to continue for a finite period of time during a suitable transition period.

5.4 Annual Disclosures made by Physicians are forwarded to the Department Chairman or President for review and approval. The Chairman or

President sends to the Office of Outside Interests his/her approval of the Physician's current disclosures in writing.

- 5.5 If a previously undisclosed Outside Interest is identified in the annual disclosure process, this Outside Interest is subject to Section 2 of this Policy.

6 Specific Activities. Notwithstanding the provisions above, the following activities comply with the requirements set forth in this section:

- 6.1 **Consulting Arrangements.** Consulting arrangements that offer to pay Physicians without any associated duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) shall be considered Gifts⁷ and are prohibited.

6.1.1. Physicians who provide consulting services enter into a consulting contract that provides specific duties and deliverables, with payment commensurate with the duties assigned and at fair market value.

6.1.2. All such consulting arrangements between Physicians and Outside Sources are reviewed and approved prior to initiation in accordance with Section 2 of this Policy.

6.1.3. This provision applies to all consulting arrangements in which a physician serves as a testifying or consulting expert in a dispute resolution proceeding (such as mediation, arbitration, administrative hearing or litigation). See also UH Policy CE-8.

- 6.2 **Speakers Bureaus.** Physicians may participate in, or receive Remuneration for, talks given through a speakers' bureau or similar frequent speaker arrangements with the following guidelines:

6.2.1 If the content of the lecture is provided by Industry, the company must have submitted the content to the FDA for approval, and the speaker obtains approval from his/her Department Chair or President. In general, if the only recognizable benefit to UH and the Physician is additional income for the Physician, the request is denied.

6.2.1.1 Physician's participation in the speakers' bureau does not create a conflict of commitment.

6.2.1.2 Non-UH employed Physicians do not need approval for participating in Speakers Bureaus but disclose participation on their annual disclosure form.

- 6.3 **Research.** A Physician serving as an investigator on a research project that is either sponsored by an Outside Source or related to the Outside Source's products with whom that Physician has a financial interest and/or a fiduciary responsibility complies with the requirements of this Policy.

- 6.3.1 Receiving support for research from Industry requires a written contract, in accordance with the policies of the UH Center for Clinical Research.
 - 6.3.2 UH collaborates with the Case Office of Outside Interests to determine the need for a management plan in accordance with Section 2.5 of this Policy.
 - 6.4 **Ghostwriting**. Ghostwriting (defined as the provision of written material, or any portion thereof, that is credited to someone other than the writer(s) of the material) is prohibited.
 - 6.5 **Gifts to Individuals**. Gifts to individuals, including Physicians and staff comply with UH Policies CE-9, 10 and 11.
 - 6.5.1 **Pharmaceutical Samples**. Drug samples are not considered Industry gifts. Physicians shall follow their respective UH entity's policies regarding acceptance and distribution of drug samples, including the UHCMC policy on Drug Samples (23.8).
 - 6.5.2 All gifts of money or in kind should be in accordance with UH Policy IRD-1 coordinated through the UH Institutional Relations and Development Department.
 - 6.6 **Meals Provided by Industry**. Meals provided by Industry comply with UH Policy CE-11 and are associated with bona fide educational, scientific, or consultative activities.
 - 6.7 **Industry-Sponsored Programs**. A Physician's attendance at an industry-sponsored program in which an Outside Source pays some or all of the physician's expenses complies with UH Policy CE-9, specifically, the provisions that address promotional training and vendor seminars. Advance approval is required.
- 7 **Conflict of Commitment**⁸. A physician may participate in outside activities, if approved in advance as outlined in Section 2 of this policy.
- 7.1 Each Physician's Department Chair or President retains discretion to limit, at any time, the amount of time devoted by such Physician to outside activities in accordance with applicable agreement(s) and policy manuals. A Physician's contract with an Outside Source specifies the expected time commitment.
 - 7.2 The total time commitment of a Physician's outside activities do not interfere with the Physician's responsibilities to UH. In addition, a Physician conducts outside activities during his/her personal time or paid time off, unless approved in advance as outlined in Section 2.
- 8 **Violations of this Policy**. Violations of this Policy may result in the full range of UH's disciplinary procedures up to and including termination. Failure to comply with this Policy or a Management Plan may also result in suspension of a Physician's research activities.

9 Interaction with Medical Staff By-Laws. This Policy supplements, and does not override, the provisions of the medical staff by-laws of UH facilities/entities. In the event of a conflict between this Policy and any medical staff by-laws, the provisions of the medical staff by-laws control.

- ¹ Outside Sources mean individuals or entities (whether profit or not-for-profit) that are involved directly or indirectly with the healthcare industry including, but not limited to, hospitals, pharmaceutical companies, medical device companies, biotech companies, software vendors, other suppliers of products, equipment or services, referral sources to UH and professional service firms (e.g., legal, accounting or consulting).
- ² Conflict of Interest means a situation in which financial or other outside interests may compromise, or appear to compromise, the judgment of a Physician regarding patient care, educational activities, research activities, business decisions, or relationships with vendors.
- ³ Financial Interest means ownership in, intellectual property rights to, remuneration from, or a fiduciary responsibility (even if uncompensated) to an Outside Source involving the individual or individual's family member(s).
- ⁴ Remuneration means direct (e.g., salary), indirect, or "in kind" compensation from an Outside Source. "In-kind" remuneration refers to compensation in the form of goods or services rather than cash or cash equivalents. Remuneration may include, but is not limited to, salary, fees, honoraria, payment for consulting services, travel expenses, stock or stock options, and other forms of payment for services from an Outside Source.
- ⁵ Family Member means spouse, domestic partner, dependent children, and/or any other dependent person living in a Physician's household.
- ⁶ Academic Institution means an institution of higher education, such as a university or school of medicine, or an academic society, such as the American Medical Association or the American Association of Pediatrics.
- ⁷ Gift means an item of any value received by a Physician for which the recipient has not provided adequate consideration in return, such as meals not associated with educational programming, cash or cash equivalents or tickets to sporting or other events.
- ⁸ Conflict of Commitment means a situation in which a Physician engages in an outside activity that interferes, or appears to interfere, with fulfillment of the Physician's obligations to UH, even if the outside activity is valuable to UH or contributes to the Physician's professional development and competence.

See Also

In the UH Policy & Procedures:

- CE-08 Conflicts of Interest
- CE-09 Vendor Gifts, Meals, Other Business Courtesies and Consulting Payment
- CE-10 Vendor Relations
- CE-11 Medical Vendor Gifts and Meals to Healthcare Professionals
- GM-21 Intellectual Property
- IRD-1 Philanthropy Facilitated Through IR&D

In the UHCMC Policy & Procedures:

- 23.8 Drug Samples

APPROVALS	
 _____ Chief Executive Officer	 _____ VP/Chief Compliance Officer
	 _____ Date
	 _____ Date

Attachment A

Criteria Considered in Approval Process

1. Is the type of agreement outlined in request and contract, i.e., ownership, intellectual property rights, consulting arrangement?
2. Consulting Arrangements:
 - a. Are the specific deliverables clearly outlined?
 - b. Is the remuneration at fair market value? (Guidance 2011 - \$3000/day or \$500/hour should be considered maximum or have support for higher payment.)
 - c. Does this arrangement conflict with other outside interests?
 - d. Is physician doing research in this clinical area, if so, Case and UH IRB must review relationship for research bias?
 - e. For speaking engagements, is there a clear benefit to UH or the speaker beyond additional compensation?
 - f. Does this engagement create a time commitment conflict?
3. Ownership Arrangements:
 - a. Will physician be able to perform all duties as outlined in UH employment contract?
 - b. Does relationship create Stark Law related issues for UH?
 - c. Does business provide services that compete with UH?
4. Intellectual Property Rights:
 - a. Must be approved by IP officer
5. Management Plan:
 - a. Does relationship require a management plan?