

CE-20 – Licensed Practitioner¹ Interactions with Outside Sources²

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 Licensed Practitioners, including UH employed residents and physicians contracted in any capacity and/or affiliated physicians on any UH medical staff (collectively “Licensed Practitioner”).
- UH encourages Licensed Practitioners 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.³
- On an annual basis, Licensed Practitioners complete a Conflicts of Interest Disclosure Questionnaire and Statement (“Disclosure Statement”) to disclose Financial Interests⁴ and participation in certain outside activities that could be a Conflict of Interest. Additionally, Licensed Practitioners complete a Request for Approval questionnaire for any new or renewing outside activity involving a personal financial interest.
- Business arrangements involving Licensed Practitioners and Outside Sources comply with this policy and, in certain circumstances explained in this policy, require advance approval.

Policy & Procedure

1. Principles.

- 1.1 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 Licensed Practitioners including UH employed residents and physicians contracted in any capacity and/or affiliated physicians acting in a leadership role (collectively “Licensed Practitioner”).
- 1.2 UH encourages Licensed Practitioners 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.

- 1.3 On an annual basis, Licensed Practitioners complete a Conflicts of Interest Disclosure Questionnaire and Statement (“Disclosure Statement”) to disclose Financial Interests⁵ and participation in certain outside activities that could be a Conflict of Interest. Additionally, Licensed Practitioners complete a Request for Approval questionnaire for any new or renewing outside activity involving a personal financial interest.
- 1.4 Business arrangements involving Licensed Practitioners and Outside Sources comply with this policy and, in certain circumstances explained in this policy, require advance approval.
- 1.5 UH requires Licensed Practitioners 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.
- 1.6 Not every Licensed Practitioner’s Financial Interest or relationship with an Outside Source is a Conflict of Interest.
- 1.7 Licensed Practitioners 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.
- 1.8 UH resolves and manages Licensed Practitioner Conflicts of Interest in an appropriate and reasonable manner, which may include a management plan.
- 1.9 A Licensed Practitioner’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.
- 1.10 Violations of this policy by a Licensed Practitioner 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, Licensed Practitioners 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 Remuneration⁶ from an Outside Source that exceeds \$1,000 from that Outside Source within a 12 month period.
 - 2.1.2 **Officer, Director, Trustee, or Policy Manager.** Licensed Practitioner or a Licensed Practitioner’s Family Member’s⁷ participation as a Director, Officer, Trustee, or Policy Manager for an Outside Source regardless of

whether Licensed Practitioner or Licensed Practitioner's Family Member receives Remuneration for participation.

2.1.3 Ownership Interest. Licensed Practitioner or a Licensed Practitioner'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. Licensed Practitioner with personal investments in a publicly-traded company recuse themselves from purchasing decisions involving the company's products or services. For Licensed Practitioners 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. Licensed Practitioner or a Licensed Practitioner's Family Member's interest in intellectual property that the Licensed Practitioner, Licensed Practitioner's Family Member or an Outside Source plans to commercialize from which the Licensed Practitioner or Licensed Practitioner'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 Licensed Practitioners request approval of outside activities at least 30 days prior to the effective date of the outside interest by submitting the Request for Approval questionnaire in the COI-Smart application.**
- 2.3 A Licensed Practitioner 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. When submitting the Request for Approval questionnaire the Licensed Practitioner provides a copy of the proposed contract between the License Practitioner and the Outside Source.**
- 2.4 Conflicts of Interest 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 Cleveland Medical Center (UHCMC). Requests by UHMG Chairs are approved by both the UHPS and UHCMC Presidents. Requests by UHMP Physicians are approved by the President of UHPS (or designee). Requests by Independent Physicians are approved by the entity President and UH Compliance & Ethics (C&E) Department.**
- 2.4.2 Requests by non-physician Licensed Practitioners must be approved by their UH supervisor at a Director level or above.**
- 2.4.2.1 The Department Chair, President(s), UH Director or above, and/or C&E Department may approve, approve with management plan, or not allow the Licensed Practitioner's request based on criteria listed in [Attachment A](#).**
- 2.4.2.2 Requests for Ownership interests in an Outside Source are reviewed by the UH Law Department and approved by the C&E Department .**
- 2.4.2.3 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.**
- 2.4.3 Criteria for Approval of Outside Activities.**
- 2.4.3.1 A Licensed Practitioner's request for approval of a relationship with an Outside Source is evaluated based upon criteria outlined in [Attachment A](#).**
- 2.5 Law Department Review.**
- 2.5.1 The UH Law Department reviews all contracts between a Licensed Practitioner and an Outside Source prior to execution of the contract.**
- 2.5.1.1 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 Licensed Practitioner. The Licensed Practitioner signing the agreement is encouraged to have the Licensed Practitioner's own attorney review the contract prior to execution of the agreement.

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

2.6.1 The C&E Department notifies a Licensed Practitioner of the decision regarding the Licensed Practitioner's approval request.

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

2.6.1.2 If approved, the Licensed Practitioner sends a copy of the executed contract to the C&E Department (instructions will be provided with the approval letter).

2.6.1.3 If approved and unless otherwise specified in a management plan, the Licensed Practitioner 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.

2.6.1.4 If approved with management plan, the Licensed Practitioner signs the management plan prior to executing the contract or beginning the outside activity.

2.6.1.5 If denied, the Licensed Practitioner may appeal the decision as described below in Section 2.8 of this Policy.

2.7 Management Plans. Approval of activities that involve a Conflict of Interest, with the individual or the institution are subject to a suitable management plan.

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

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

2.7.1.2 Requiring the individual to inform certain persons or institutions (such as patients, journals, professional audiences) about the Outside Interest as required by the management plan;

2.7.2 The Physician's Department Chair or President(s), the non-physician

Licensed Practitioner's supervisor, or the C&E Department may determine that a management plan is necessary.

2.7.3 In determining whether a management plan is required, the Physician's Department Chair or President(s), the non-physician Licensed Practitioner's supervisor, or the C&E Department, 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 Licensed Practitioner's agreements, when applicable. Additional factors include if intellectual property rights or ownership are involved.

2.7.4 If the Licensed Practitioner has a current research-related management plan with Case Western Reserve University (CWRU), UH adopts this management plan and may enter into an additional management plan if appropriate.

2.7.5 The C&E Department maintains the management plan for the duration of the agreement and sends a copy to the Department Chair, UHPS/UHCMC President, or the non-physician Licensed Practitioner's supervisor as applicable.

2.8 Appeal of Decision.

2.8.1 Licensed Practitioners who have been denied approval of their request to participate in an outside activity may appeal the decision to the UH Chief Compliance Officer (CCO).

2.8.2 The Licensed Practitioner's appeal should be in writing and sent to compliance@uhhospitals.org. The appeal includes compelling circumstances why the Licensed Practitioner disagrees with the decision and reasons for why a reversal of the decision should be granted.

2.8.3 The CCO 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 Institution⁸ 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 Licensed Practitioners complete a Conflict of Interest questionnaire as directed by the C&E Department.**
- 4.2 Licensed Practitioners submit a Request for Approval questionnaire prior to engaging in any new or renewing activity that requires approval, as outlined in this Policy.**
- 4.3 The Medical Staff Credentialing Department notifies the C&E Department that the Licensed Practitioner submitted an application and requires a Conflict of Interest questionnaire to be completed.**

5. Review of Disclosures.

- 5.1 Acting under the direction of the CCO, the C&E Department conducts an initial review of all disclosures. If necessary, the C&E Department obtains additional information from the Licensed Practitioner or other individuals who possess relevant information regarding the Licensed Practitioner's disclosure.**
- 5.2 If the Licensed Practitioner conducts research as a faculty member of CWRU, UH works collaboratively with the CWRU Conflict of Interests Committee to review the reported activities and management plan(s).**
- 5.3 In the case of a Licensed Practitioner who is newly hired at UH, the CCO may permit a prohibited Conflict of Interest to continue for a finite period of time during a suitable transition period.**
- 5.4 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 Licensed Practitioners without any associated duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) are considered Gifts⁹ and are prohibited.**
 - 6.1.1 Licensed Practitioners 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 new and renewing consulting arrangements between Licensed Practitioners 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 Licensed Practitioner 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, Conflicts of Interest.

- 6.2 Speakers Bureaus.** Licensed Practitioners 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 industry sponsor obtain FDA approval prior the speaking engagement.
 - 6.2.1.1** Licensed Practitioner's participation in the speakers' bureau does not create a Conflict of Interest.
 - 6.2.1.2** Prior to review by UH's Law and C&E Departments, Licensed Practitioners obtain prior approval from Physician's Department Chair or President(s), or the non-physician Licensed Practitioner's supervisor and provides C&E with an explanation how involvement in the Speakers' Bureau provides a clear benefit to UH and/ or the contribution to the Licensed Practitioners professional development.
- 6.3 Research.** A Licensed Practitioner 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 Licensed Practitioner 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 UHCMC Center for Clinical Research and Technology.
 - 6.3.2** UH collaborates with the CWRU Conflict of Interests Committee Office 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 Licensed Practitioners comply with UH Policies CE-9, CE-10 and CE-11.
- 6.5.1 Pharmaceutical Samples.** Drug samples are not considered Industry gifts. Physicians follow their respective UH entity's policies regarding acceptance and distribution of drug samples, including UHCMC Policy 11.23.8, Drug Samples.

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 Commitment¹⁰. A Licensed Practitioner 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 or non-physician Licensed Practitioner's supervisor retains discretion to limit, at any time, the amount of time devoted by such Licensed Practitioners' outside activities in accordance with applicable agreement(s) and policy manuals. A Licensed Practitioner's contract with an Outside Source specifies the expected time commitment. In general, it is expected that a Licensed Practitioner would not be permitted to devote more than 20% of his/ her time to outside activities.

7.2 The total time commitment of a Licensed Practitioners' outside activities do not interfere with the Licensed Practitioners' responsibilities to UH. In addition, a Licensed Practitioner 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 Licensed Practitioner'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 For the purposes of this policy, Licensed Practitioner means any individual licensed in Ohio to prescribe medications, durable medical equipment, supplies, or devices.

² 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). Outside Source also includes any third party acting on behalf of the individuals or entities as the paying agent to the Licensed Practitioner.

- ³ Conflict of Interest means a situation in which financial or other outside interests may compromise, or appear to compromise, the judgment of a Licensed Practitioner regarding patient care, educational activities, research activities, business decisions, or relationships with vendors, loyalty to UH or ability to perform his or her responsibilities to a UH entity.
- ⁴ Financial Interest means ownership in, intellectual property rights to, remuneration from, or a fiduciary responsibility (even if uncompensated), or receipt of gifts, gratuities or to her business courtesies (e.g. meals, entertainment) greater than \$150 from an Outside Source involving the Licensed Practitioner or the Licensed Practitioner's family member(s).
- ⁵ 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.
- ⁶ Family Member means spouse, domestic partner, dependent children, and/or any other dependent person living in a Licensed Practitioner's household.
- ⁷ 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.
- ⁸ Gift means an item of any value received by a Licensed Practitioner 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.
- ⁹ Conflict of Commitment means a situation in which a Licensed Practitioner engages in an outside activity that interferes, or appears to interfere, with fulfillment of the Licensed Practitioner's obligations to UH, even if the outside activity is valuable to UH or contributes to the Licensed Practitioner's professional development and competence.

See Also

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

Electronically approved by Tom Zenty, President and CEO of UH – March 8, 2016
Electronically approved by Kim Bixenstine, Chief Compliance Officer – March 8, 2016

Attachment A

Criteria Considered in Approval Process

1. Is the type of agreement outlined in the 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 Licensed Practitioner doing research in this clinical area? If so, CWRU and UH IRB must review the 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 the Licensed Practitioner be able to perform all duties as outlined in a UH employment contract?
 - b. Does the relationship create Stark Law related issues for UH?
 - c. Does the business provide services that compete with UH?
4. Intellectual Property Rights:
 - a. Has the intellectual property rights issue been approved by UH Intellectual Property Officer?
5. Management Plan:
 - a. Does relationship require a management plan?

Electronically approved by Tom Zenty, President and CEO of UH – March 8, 2016
Electronically approved by Kim Bixenstine, Chief Compliance Officer – March 8, 2016