

**UPMC
POLICY AND PROCEDURE MANUAL**

POLICY: HS-EC1702 *
INDEX TITLE: Ethics & Compliance

SUBJECT: Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Personnel Employed by UPMC at all United States based Locations

DATE: July 28, 2022

I. POLICY

It is the policy of UPMC that clinical decision-making, education, research, health care operations, and administrative activities be free from influence created by improper financial relationships with, or gifts provided by, Industry. For purposes of this policy, “Industry” is defined as all pharmaceutical manufacturers, and biotechnology, medical device,¹ and hospital equipment supply industry entities and their representatives. Clinicians and employees should not be the target of commercial blandishments or inducements – great or small – the costs of which are ultimately borne by our patients and the public at large, or UPMC. These general principles should guide all potential relationships or interactions between UPMC personnel and Industry representatives. The following specific limitations and guidelines are directed to certain specific types of interactions. For other circumstances, UPMC personnel should consult in advance with their Administrator or the Conflicts of Interest Office (conflicts@upmc.edu) to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of UPMC shall be subject to other policies adopted from time to time by UPMC or foundations fundraising on its behalf.

Links to policies referenced within this policy can be found in Section VI.

II. PURPOSE

Interaction with Industry can further the advancement of science and innovation; however, Industry influence could also result in unacceptable conflicts of interest, actual or perceived, that may lead to:

1. Increased costs of healthcare,
2. Compromise of patient safety,
3. Compromise of business judgment,
4. Negative socialization of student and trainees,

¹ For purposes of this Policy, the definition of “medical devices” will follow the definition and any available guidance related thereto of the Federal Safe Medical Device Act of 1990, as amended, ([21 CFR Part 821 Medical Device Tracking Requirements](#))

5. Bias of research results; and,
6. Diminished confidence and respect among patients, the general public and regulatory officials.

This policy has been designed on the basis of the best available literature on conflict of interest and is intended to provide a set of guiding principles that members of the UPMC community and representatives of Industry can use to assure that their interactions result in optimal benefit to clinical care, education, research, health care operations, administrative activities, and maintenance of the public trust. This policy is designed to guide the behavior and practices of Industry, and the behavior of UPMC personnel. While valuable and meaningful interactions between Industry and academic medical centers can occur, the provision of gifts, food, or other associated items add nothing to the substance of the exchange and may leave both parties subject to questions of integrity and commitment to professional practice, operational, and administrative responsibilities.

III. SCOPE

This policy applies to all individuals employed and/or engaged by fully integrated UPMC entities including *but not limited to* those within the Insurance Services Division, the Physician Services Division, and the hospital and ambulatory surgery facilities noted below. While this policy addresses many aspects of Industry interaction, it supplements the existing UPMC policies, including but not limited to:

- UPMC Conflict of Interest and Commitment – General Obligations Policy No. HS-EC1700
- Conflict of Interest in Clinical Research Policy No. HS-EC1701
- UPMC Guidelines for Purchasing Materials, Goods and Services Policy No. HS-MM0300

In all cases where this policy is more restrictive than a UPMC conflict of interest policy, this policy shall control.

Individuals who are employed by both UPMC and the University of Pittsburgh must also consult any applicable University COI policies, particularly as they apply to research conflict of interest.

This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about company products, even though such personnel are not classified in their company as “sales or marketing.”

[Check all that apply]

- | | |
|--|--|
| <input checked="" type="checkbox"/> UPMC Children's Hospital of Pittsburgh | <input checked="" type="checkbox"/> UPMC Pinnacle Hospitals |
| <input checked="" type="checkbox"/> UPMC Magee-Womens Hospital | <input checked="" type="checkbox"/> UPMC Carlisle |
| <input checked="" type="checkbox"/> UPMC Altoona | <input checked="" type="checkbox"/> UPMC Memorial |
| <input checked="" type="checkbox"/> UPMC Bedford | <input checked="" type="checkbox"/> UPMC Lititz |
| <input checked="" type="checkbox"/> UPMC Chautauqua | <input checked="" type="checkbox"/> UPMC Hanover |
| <input checked="" type="checkbox"/> UPMC East | <input checked="" type="checkbox"/> UPMC Muncy |
| <input checked="" type="checkbox"/> UPMC Hamot | <input checked="" type="checkbox"/> UPMC Wellsboro |
| <input checked="" type="checkbox"/> UPMC Horizon | <input checked="" type="checkbox"/> UPMC Williamsport |
| <input checked="" type="checkbox"/> UPMC Jameson | <input checked="" type="checkbox"/> Divine Providence Campus |
| <input checked="" type="checkbox"/> UPMC Kane | <input checked="" type="checkbox"/> UPMC Lock Haven |
| <input checked="" type="checkbox"/> UPMC McKeesport | <input checked="" type="checkbox"/> UPMC Cole |
| <input checked="" type="checkbox"/> UPMC Mercy | <input checked="" type="checkbox"/> UPMC Somerset |
| <input checked="" type="checkbox"/> UPMC Northwest | <input checked="" type="checkbox"/> UPMC Western Maryland |
| <input checked="" type="checkbox"/> UPMC Passavant | |
| <input checked="" type="checkbox"/> UPMC Presbyterian Shadyside | |
| <input checked="" type="checkbox"/> Presbyterian Campus | |
| <input checked="" type="checkbox"/> Shadyside Campus | |
| <input checked="" type="checkbox"/> UPMC Western Psychiatric Hospital | |
| <input checked="" type="checkbox"/> UPMC St. Margaret | |

Provider-based Ambulatory Surgery Centers

- UPMC Altoona Surgery Center
- UPMC Children's Hospital of Pittsburgh North
- UPMC St. Margaret Harmar Surgery Center
- UPMC South Surgery Center
- UPMC Center for Reproductive Endocrinology and Infertility
- UPMC Digestive Health and Endoscopy Center
- UPMC Surgery Center – Carlisle
- UPMC Surgery Center Lewisburg
- UPMC Pinnacle Procedure Center
- UPMC West Mifflin Ambulatory Surgery Center
- UPMC Community Surgery Center

Free-Standing Ambulatory Surgery Facilities:

- UPMC Hamot Surgery Center (**JV**)
- Hanover Surgicenter
- UPMC Leader Surgery Center (**JV**)
- UPMC Specialty Care York Endoscopy
- Susquehanna Valley Surgery Center (**JV**)
- West Shore Surgery Center (**JV**)

IV. PROCEDURE

Specific Activities

A. Gifts and Provision of Meals

1. UPMC personnel shall not accept or use personal gifts (including but not limited to food, tickets to sporting or other events, etc.) from representatives of Industry, regardless of the nature or dollar value of the gift.²
2. Meals or other hospitality funded or provided directly by Industry, i.e., not through an approved agreement with UPMC, may not be offered in any facility owned and operated by UPMC.
3. Modest meals provided incidental to attendance at an off-campus event that complies with the provisions of subsection F (Industry Sponsored Meetings or Industry Support for Off-Campus Meetings) below, may be accepted.
4. Industry wishing to make charitable contributions to UPMC must contact the Medical and Health Sciences Foundation or other charitable foundations legally organized to support UPMC hospitals or other UPMC entities. Such contributions shall be subject to any applicable policies maintained by UPMC and the receiving organizations.

B. Consulting Relationships

1. Consulting arrangements that pay UPMC personnel a guaranteed amount without any associated duties (such as participation in scientific advisory boards that do not regularly meet and provide scientific advice) shall be considered gifts and are consequently prohibited.
2. Consulting contracts must provide specific tasks and deliverables, with payment commensurate with the tasks assigned and subject to limitations established by UPMC from time to time. All such arrangements between individuals or units and outside commercial interests must be reviewed and approved prior to initiation in accordance with appropriate UPMC policies and guidelines.
3. Consulting services shall be utilized to promote generally accepted standards for clinical care or to advance scientific research and/or other activities consistent with UPMC's mission.

² For gifts or gratuities from UPMC patients, their relatives, caregivers or visitors, please consult the [UPMC Code of Conduct](#).

4. Consulting services shall not be used for commercial marketing or promotional purposes. Consultants' contributions of clinical care or scientific information may be used to inform Industry commercial strategies and initiatives.
5. Training services provided by a Consultant for Industry shall not be used for marketing or promotional purposes. Training services shall be to enhance skills, to improve patient-and member-outcomes and/or operational efficiencies, and/or further other activities consistent with UPMC's mission.
6. Industry may not pay for a consultant's time spent traveling if the Consultant is employed by UPMC or dually employed by UPMC and the University. Reasonable travel expenses (e.g., hotel charges, airfare, mileage, etc.) may be paid or reimbursed by Industry provided that such expenses are incurred in relationship to providing specific contracted tasks and deliverables.
7. Industry consultants shall not negotiate or discuss commercial business, including but not limited to purchasing or procurement, on behalf of UPMC with Industry for whom they consult.
8. Content of all presentations and related materials presented by consultants shall be designed to promote a balanced assessment of the current science and treatment options. Individuals consulting with Industry shall make clear that the views expressed are the individual's and not those of UPMC. In addition, consultants shall prominently disclose in the presentations that they receive compensation from the Industry party whose technology or products are discussed.
9. Prior written approval of the appropriate supervisor within UPMC is required for any outside consulting.
10. Dually employed individuals may also be subject to other approvals as defined by University of Pittsburgh policies.
11. UPMC reserves the right to require employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with UPMC policies.
12. All Consulting arrangements must be disclosed per policy³ by completing a Conflict Disclosure Form, which may be accessed at www.mydisclosures.pitt.edu.

³ HS-EC1700

C. Drug Samples

1. Acceptance of branded drug and other branded samples is prohibited unless approved by the UPMC Conflict of Interest Committee.
2. Practices are permitted the use of approved automated dispensing systems for generic products.
3. Over the counter products may be accepted and distributed by UPMC offices, subject to approval by appropriate administrators.

D. Site Access

1. UPMC's Supply Chain Management will support a registry to assist in the management of site access by Industry representatives for appropriate purposes as governed by UPMC's Vendor Access Policy HS-FM0222.
2. Vendors, as defined by policy HS-FM0222, may only access UPMC hospital facilities if the company with which they are associated has registered with the UPMC Vendor Access and ID system in place and they have been specifically invited to meet with an individual health care provider or a group of health care providers for a particular purpose.
3. Representatives may only access UPMC physician offices when specifically invited in advance to meet with an individual health care provider or a group of health care providers for a particular purpose.
4. Individual physicians or groups of physicians or other health care professionals may request a presentation by or other information from a company through UPMC's Supply Chain Management department.
5. Representatives may not conduct business in patient care areas (inpatient or outpatient), in practitioners' office areas, or other areas of UPMC clinical facilities.
6. All Industry personnel seeking sales or vendor relationships must work directly with UPMC's Supply Chain Management department.
7. While in UPMC clinical facilities, all Industry representatives must be identified by name and current company affiliation in a manner determined by such department or facility, as applicable.
8. All Industry representatives with access to UPMC clinical facilities and personnel must comply with institutional requirements for training in ethical standards and organizational policies and procedures.

9. On-site vendor fairs intended to showcase Industry products may be permitted if approved by the UPMC's Supply Chain Management, but only in designated areas or locations in which no clinical care is delivered or in which no research is conducted. Such events must comply with the "no gifts" provisions of Sections A and C. of this policy. In such situations, vendors are not permitted to distribute free samples, free meals, raffle tickets or any other gifts to attendees.

E. Support of Continuing Education in the Health Sciences

Industry support of continuing education ("CE") in the health sciences can provide benefit to patients by ensuring that the most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing:

1. CE events hosted or sponsored by UPMC or affiliates must comply with applicable ACCME Standards for Commercial Support of Educational Programs or standards required by other health professional accreditor, as determined by the Center for Continuing Education in the Health Sciences ("CCEHS") and whether or not CE credit is awarded.
2. Industry funding for such UPMC programming should be used to improve the quality of the education provided and should not be used to support hospitality, such as meals, social activities, etc.
3. All agreements for Industry support must be negotiated through and executed by CCEHS and must comply with all policies for such agreements.
4. Any such educational program must be open on equal terms to all eligible practitioners and cannot be limited to attendees selected by the company sponsor(s).
5. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

F. Other Industry Sponsored Educational Meetings or Industry Support for Educational Off-Campus Meetings

1. UPMC providers or staff may participate in or attend Industry-sponsored educational meetings or other off-campus educational meetings where Industry support is provided, so long as:
 - a. The activity promotes generally accepted standards of clinical care and/or advance scientific research;

- b. If the UPMC representative is an attendee, Industry does not pay attendees' travel and attendance expenses, except as provided in section G below;
 - c. Attendees cannot accept gifts or other compensation for their attendance; and,
 - d. Meals provided at the event are modest to the best of attendee's knowledge.
- 2. In addition, if a UPMC representative is participating as a speaker:
 - a. All lecture content is determined by the UPMC speaker and reflects a balanced assessment of the current science and treatment options, and the speaker makes clear that the views expressed are the views of the speaker and not UPMC;
 - b. Compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium not to exceed \$2,500 per event.
- 3. Support payments received from Industry is likely to be reported to the CMS Open Payments Portal by Industry as required by the Physician Payments Sunshine Act. Any known support received from Industry should be disclosed per policy⁴ by completing a Conflict Disclosure Form, which may be accessed at www.mydisclosures.pitt.edu.

G. Industry Support for Scholarships or Fellowships or Other Support of Students, Residents or Trainees

UPMC, through the UPMC ME Office, may accept Industry support for scholarships or discretionary funds to support trainee travel or non-research funding support, provided all of the following conditions are met:

- 1. Industry support for scholarships and fellowships must comply with the following:
 - a. They must comply with all UPMC requirements, or if dually employed, all UPMC and University of Pittsburgh requirements for such funds, including the execution of an approved budget and written gift agreement through the Medical and Health Sciences Foundation, and be maintained in an appropriate restricted account, managed as determined by the UPMC ME Office.
 - b. Selection of recipients of scholarships or fellowships will be within the sole discretion of the school or training program in which the student or trainee is enrolled. In the case of an ACGME accredited training

⁴ HS-EC1700

program, the training program must notify the Designated Institutional Official.

- c. The training program or school will maintain written documentation of the selection process.
 - d. Recipients will be offered and have the right to decline Industry support for their position and will be notified by UPMC ME via the Trainee Notification of Industry Funding Letter in accordance with established processes.
2. Industry support for other trainee activities, including travel expenses or attendance fees at conferences:
- a. Must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be maintained under the direction of the clinical department and/or Hospital Administration (as specified in the funding agreement).
 - b. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit.
 - c. Attendees must be selected by the department or training program based upon merit and/or financial need, with documentation of the selection process provided with the request.
 - d. Approval of particular requests shall be at the discretion of the Department Chair, Hospital Administration and/or Program Director, or other individual with appropriate institutional authority with a required notification to the Designated Institutional Official.
 - e. Recipients will be notified of Industry support by UPMC ME via the Trainee Notification of Industry Funding Letter in accordance with established processes.

H. Frequent Speaker Arrangements (Speakers Bureaus) and Ghostwriting

1. A speakers bureau is a collection of healthcare professionals, paid or volunteering, organized to speak about a particular drug or device product or a disease state on behalf of the company to other healthcare professionals. "Speakers bureaus" sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming and place the speaker at risk of violating anti-kickback laws. While many speaking or lecture engagements are permissible and valuable as

a source of education, inappropriate speaker bureaus are not permitted. Questionable speaker bureaus may involve, several or more, among others, of the following characteristics:

- The company requires the speaker to undergo mandatory training prior to a speaking engagement;
- The company supplies the educational materials to which the presenter must adhere;
- The content of the presentation is not based on the best available scientific evidence and/or little or no substantive information is presented;
- There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;
- Company offers to compensate in excess of fair market value and/or involves repeated speaking engagement on the same topic that may result in excessive compensation;
- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);
- The company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether the event meets the criteria set forth in Section F of this policy, relating to Industry Sponsored Meetings. UPMC personnel may not participate in, or receive compensation for, talks given through a speakers bureau or similar frequent speaker arrangements if:

- (a) the events do not meet the criteria of Section F; *or*,
- (b) are characteristic of a questionable speakers bureau.

Speaking relationships with company or company event planners are treated as consulting relationships and subject to review and approval of the participant's administrator, Department Chair as delineated in Section B, Consulting Relationships and must be disclosed per policy⁵ by completing a Conflict Disclosure Form, which may be accessed at www.mydisclosures.pitt.edu.

2. Ghostwriters can be engaged by Industry and other entities to create content, such as a journal article for which someone else is identified as the author. The resulting documents may be part of a marketing campaign to promote a product or highlight the condition it treats. It is not appropriate for UPMC personnel to be funded by Industry to create content for which they are not

⁵ HS-EC1700.

given attribution, nor is it permissible to claim authorship for content that they have not developed.

I. Other Industry Support

UPMC, through the UPMC Office of Sponsored Programs and Research Support has established policies and contract forms to permit Industry support of basic and clinical research in a manner consistent with UPMC's non-profit mission. True philanthropic gifts from Industry may be accepted through the Medical and Health Sciences Foundation or UPMC hospital foundations, provided that receipt of such gifts is periodically reported to the UPMC Conflict of Interest Committee in such format and frequency as it may require.

V. REPORTING AND ENFORCEMENT

A. UPMC personnel shall report their outside relationships with Industry using the Conflict Disclosure form, available online at www.mydisclosures.pitt.edu; at least annually and more often as needed to disclose new and update existing relationships.

1. Alleged violations of this policy shall be investigated by the UPMC Ethics and Compliance Office.
2. Suspected violations of this policy shall be referred to the individual's immediate supervisor who shall determine what actions, if any, shall be taken.
3. The UPMC Ethics and Compliance Office shall also be notified of suspected violations by UPMC personnel.
4. Violations of this policy by UPMC employees may result in the following actions (singly or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, and whether the violator knowingly violated the policy or attempted to hide the violation:
 - Counseling of the individual involved;
 - Written reprimand, entered into the violator's employment or faculty record;
 - Banning the violator from any further outside engagements for a period of time;
 - Requiring that the violator return any monies received from the improper outside relationship;
 - Requiring the violator to complete additional training on conflict of interest;
 - Removing the violator from supervision of trainees or students;
 - Revoking the violator's UPMC hospital privileges;
 - Fines;
 - Termination for cause;

- Other applicable actions.

Any disciplinary action taken hereunder shall follow the established procedures of the University and/or UPMC.

- B. Industry companies or their representatives who violate this policy may be subject to penalties outlined in UPMC Guidelines for Purchasing Materials, Goods and Services Policy No. HS-MM0300, or other applicable UPMC policies, including HS-IS0147 as it pertains to unwanted or unsolicited emails and other electronic messaging, as well as other actions or sanctions imposed at the discretion of the President of UPMC. Violation of any of the above procedures by representatives shall result in disciplinary action which may include but shall not be limited to the following:
1. First violation: Verbal and written warning to the company and their representative; written notification to district manager or representative's supervisor.
 2. Second violation: Suspension of company, representative, and all other company sales/marketing representatives from UPMC for six months.
 3. Third violation: Suspension of company, representative, and all other sales and marketing representatives of the company from UPMC for one year or more. A review of multi-source products obtained from the company will be conducted.

Representatives found trespassing as defined in this policy will be escorted from the premises and their companies notified as appropriate.

VI. **POLICIES REFERENCED WITHIN THIS POLICY**

[HS-EC1700 Conflict of Interest – General Obligations](#)

[HS-EC1701 Conflict of Interest in Clinical Research](#)

[HS-EC1900 Code of Conduct](#)

[HS-MM0300 Guidelines for Purchasing Materials, Goods and Services](#)

[HS-IS0147 Electronic Mail, Messaging, and Texting](#)

SIGNED: Catherine Yunk
Chief Audit and Chief Compliance Officer

ORIGINAL: February 15, 2008

APPROVALS:

Policy Review Subcommittee: July 14, 2022

Executive Staff: July 28, 2022

PRECEDE: November 2, 2020

SPONSOR: Chief Audit and Chief Compliance Officer

*** With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.**