



# Industry Relationships Policy (IRP) Frequently Asked Questions

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# General Topics

## What is the definition of “medical device” for purposes of this policy?

For purposes of this policy, the term “medical device” refers to any device that is tracked pursuant to the federal Safe Medical Device Act, which generally includes devices that are implantable or life-sustaining.

## How is this policy being enforced?

With respect to violations by Industry representatives, enforcement shall be the responsibility of the UPMC Supply Chain Management and the University’s Purchasing Department. With respect to UPMC employees, violations of the policy shall be handled first by the individual’s immediate supervisor and the UPMC Ethics and Compliance Office; in the case of SOHS personnel, violations of the policy shall be handled first by the individual’s dean and department chair; or both (for dual status personnel). Existing policies of UPMC and the University related to employment actions shall apply to any action taken, including any provisions in those policies for appeal of decisions.

## What is the guidance surrounding authorship and ghostwriting?

The Industry Relationship Policy prohibits SOHS and UPMC personnel from lending their name to articles or presentations ghostwritten by industry. The [Uniform Requirements for Manuscripts Submitted to Biomedical Journals](#) provides detailed guidance about the accepted standards for being listed as an author on a submitted manuscript. Individuals shall have made specific and substantial contributions in the design, conduct, analysis, and writing of a manuscript in order to be listed as an author. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Many journals now require the corresponding author to describe the roles of each author. In addition, each author is expected to take public responsibility for the integrity and accuracy of the publication.

Access to litigation documents has revealed an unsavory apparent disregard for authorship requirements by members of the academy in collaboration with for-profit sponsors of clinical trials. Academics who have had little or no participation in the clinical trial have been asked to add their and their institutions’ good names to a manuscript that is in essentially final form, having been writing by the sponsor. In addition to being the ethical antithesis of the precepts of scientific reporting, such actions may also result in very public embarrassment.

A series of articles in the *Journal of the American Medical Association* provides both data and discussion on this topic:

[Editorial: Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence](#)

[Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation](#)

[Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents From Rofecoxib Litigation](#)

## Where/how are medication samples allowed to be dispensed?

In 2008 UPMC surveyed all of its outpatient facilities to determine which sites would continue to maintain and dispense medication samples provided by Industry. For those sites that opted to provide samples to their patients,

training was undertaken to assist them in complying with regulatory requirements for inventory management and proper dispensing.

A working group composed of physicians, pharmacists, and administrators from across the Health System developed a plan to centralize the receipt of samples from manufacturers. Under this plan, offices are able to select a supply of the medications they need from the inventory. Samples are delivered to sites through couriers or overnight express service.

These sites are permitted to invite Industry representatives who have completed required educational modules to deliver samples to their offices. Representatives must comply with all aspects of the IR Policy, including prohibitions on gifts and meals.

### For More Information

Contact the Information Center at 412-647-2406 or email [IndustryRelation@upmc.edu](mailto:IndustryRelation@upmc.edu). The Policy and other supporting materials can be found on the [Pitt COI website](#).

For the October 27, 2008 announcement of the eSample Center launch, [click here](#).

For a Step-by-Step Guide and a Tutorial about the eSample Center, visit: <http://industryrelations.infonet.upmc.com/training.htm>

For FAQs about the eSample Center: <http://industryrelations.infonet.upmc.com/faqs.htm>

## Can Industry support continuing education and community education programs?

Under the Industry Relationship Policy, Industry can provide funds to the University or UPMC for accredited or non-accredited activities (including training programs on new devices) through guidelines established in the [Accreditation Council for Continuing Medical Education Standards for Commercial Support](#). According to these standards, the University and/or UPMC must retain control over the content and faculty selection, and presentations must allow for balanced discussion of alternative approaches, as appropriate. Industry can provide financial support through an educational grant but cannot directly pay for food, social events, faculty honoraria, or any other costs associated with the activity. Industry-sponsored exhibits are permitted in off-campus and certain on-campus locations for the purpose of disseminating information about products and services. However, the distribution of gifts is not permitted.

Further guidance on more specific types of activities can be found at the following FAQs:

- [Vendor's equipment in UPMC operating room](#)
- [Industry support of professional organization's annual meeting](#)
- [Vendor support for attendance at off-site meeting](#)

## What are the appropriate procedures for establishing SOHS/UPMC/Vendor relationships?

The following guidance relates to acceptable procedures for inviting Industry Representatives to meetings at the Schools of the Health Sciences ("SOHS") and/or UPMC premises.

All Industry Representatives seeking a vendor relationship with the SOHS or UPMC must first complete a mandatory training course, which is available online at: <http://cme.hs.pitt.edu> and after login select Vendor Training. New users must first create an account.

Registered representatives may then be invited by SOHS or UPMC, via the appropriate Purchasing Department, to schedule a meeting to discuss a new drug, device, or hospital supply item.

- [Click here for appropriate procedure.](#)

This training and registration process is NOT required for 1) visits from Industry auditors reviewing Industry-sponsored clinical trials; or 2) visits to initiate or review research projects.

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# Industry Presence at University of Pittsburgh and UPMC Facilities

Can a faculty physician or staff member invite a representative from Industry to a faculty meeting to discuss a new drug or device that is under consideration for clinical use?

A SOHS or UPMC employee may request, via the appropriate organization's purchasing department, to schedule a presentation by an Industry representative. If the product will be purchased with University funds under a University account number, see the University's Purchasing website [www.bc.pitt.edu/purchasing](http://www.bc.pitt.edu/purchasing) for instructions; otherwise, contact UPMC's Supply Chain Management department <http://purchasing.upmc.com> or [customerservicesupplychain@upmc.edu](mailto:customerservicesupplychain@upmc.edu). The Industry representative must be registered with the appropriate organization's purchasing department, must have completed required training, and must comply with badging requirements. Any such presentation should allow time for attendees to fully discuss questions related to the data presented, and no gifts may be provided to attendees.

Can a supplier who does NOT meet the definition of Industry under the policy conduct sales activities, such as presentations and shows, at my facility without registration?

Yes. If the supplier is not in the pharmaceutical, biotechnology, medical device, or hospital equipment supply industries, the supplier must comply with the existing University and UPMC purchasing policies, but is not subject to the additional requirements of the Industry Relationship Policy.

What facilities have controlled access for Industry representatives?

All SOHS facilities and all UPMC clinical facilities are subject to the access restrictions.

If the Industry supplier is under a long-term enterprise-wide contract or a long-term department contract, do I need to process a supplier visit request for each visit?

The Industry vendor need only register as a corporate entity once, but each visit by a representative must be requested and approved prospectively by the responsible purchasing department.

Our department will be using a newly approved medical device, and on-site training by the manufacturer is required. How do we arrange for this in a way that is consistent with the policy?

Training on new medical devices may be provided on-site, as long as the Industry representative has first registered with UPMC Supply Chain Management, completed the necessary training, and is following badging requirements. Appointments will normally be made for such purposes as in-service training of personnel for research or clinical equipment already purchased, or the evaluation of new purchases of equipment, devices, or related items

A device, biologic, and/or drug manufacturer would like to conduct a training session using the company's product(s) in our animal facilities. Is this permissible, and what approvals are needed?

In general, company-sponsored, product-specific training in University or UPMC facilities is not permitted under the Industry Relationship Policy. In particular, use of animals for product demonstration or product training would not be acceptable under University IACUC policies. Where UPMC has already approved a particular device through its Value Analysis Program, and that device is in use in clinical settings, training of residents and staff on its use should be conducted by UPMC physicians in that setting.

If UPMC or University personnel wish to design and control their own training course, and if an animal model is absolutely the only way to accomplish this training, and the training is capable of and necessary to correct identified and quantified serious safety issues with the particular procedures or products in question, such a course may be approvable. In this latter case, Industry support may be allowable, subject to an appropriate agreement being negotiated through the University with the funding source.

Agreements that seek to lease or rent the University facilities, or which permit instruction by Industry representatives, or which include third parties invited by Industry representatives, will not be approved.

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# Accepting Gifts or Support from Industry

We are holding our annual departmental retreat; can we solicit funds from drug or device manufacturers to defray our costs?

No. Departmental meetings are an administrative expense and should be paid for with departmental funds. Contributions from Industry to pay for internal meetings present the same issues as direct provision of meals and are not permitted. Solicitation of philanthropic gifts from Industry for support of research or for support of educational programs may be coordinated through the Medical and Health Sciences Foundation.

We are having a fundraising event at which corporate sponsors will be invited to buy tables. Is this permitted under the policy?

Fundraising social events that are open to the general public, with ticket payments going to a general philanthropic goal (e.g., a scholarship fund, a general purposes fund for a particular school, etc.) are not prohibited by the policy. Departments should coordinate closely with the Medical and Health Sciences Foundation in the planning and marketing of such events.

Our professional organization's annual meeting is supported by Industry sponsors; may I attend this meeting?

Provided that the meeting is designed to promote evidence-based clinical care, and/or to advance scientific research, and industry support is prominently disclosed, attendance would not be prohibited by the policy.

Attendees must pay their own expenses and may not receive gifts or compensation for attendance. Any meals provided must be incidental to the event and modest in cost. Logo incidentals of nominal value (such as meeting folders, binders, or canvas bags) that are provided as a matter of course to all attendees may be accepted for use at the conference but should not be utilized in SOHS or UPMC clinical areas.

A company wants to make an unrestricted gift for my use. Is that a potential conflict of interest?

While true philanthropic gifts, even when designated for the support of a specific investigator, are permitted under the Industry Relationships Policy, such gifts may still result in a conflict of interest for the investigator who is the beneficiary of the gift. As a threshold matter, unrestricted gifts in support of research of a named investigator will receive close scrutiny to ensure that there are no material transfer agreements, data transfer agreements, license agreements, pending IRB or IACUC protocols involving technology of interest to the company, or other relationships that suggest that the gift should more properly be categorized as a research grant. In cases where the Health Sciences Foundation and/or the Office of Research determine that the gift should more properly be considered a grant, the investigator's department will be directed to develop an appropriate contract and budget through the Office of Research.

Where the gift is determined to be truly philanthropic, under FDA conflict of interest rules, you may have a reportable financial interest if you are serving as an investigator of a clinical investigation subject to FDA regulations. Under FDA regulations, if you are the beneficiary of any unrestricted grant or other payment from the sponsor of that FDA regulated study, you will have a reportable conflict of interest if the cumulative amounts of all payments and unrestricted grants designated for your benefit and received during the study and for one year following total \$25,000 or more. The FDA regulations take into consideration all payments, including consulting

payments, unrestricted gifts for your benefit, and provision of equipment, unless the equipment is necessary for the conduct of the study.

In addition, if you are a physician or dentist, and therefore covered by the reporting obligations of the Physician Sunshine Payment Act, gifts received for your benefit may be reportable by the industry donor to Centers for Medicare and Medicaid Services (“CMS”). CMS will report all such payments as part of an online, searchable database.

### Will the prohibition on gifts in the policy prohibit my laboratory from receiving donated drugs for use in basic research?

No. Materials donated for research use may be received by the University under an appropriate Material Transfer Agreement.

### Our office has multiple anatomical models which have been provided to us for purposes of patient education, and these models also bear corporate logos. Does this policy require us to remove these items from our offices?

No; these items are acceptable because they primarily entail a benefit to patients; they are intended for patient education and may be retained. In accepting any new models from Industry, care should be taken to indicate to the offering company that such items need to be directly shipped, unless a manufacturer’s representative is invited to the office in accordance with the policy’s requirements. Logos or company advertising on the models should be removed or otherwise covered.

### A vendor has offered to underwrite the cost of travel, lodging, and other expenses in connection with my attendance at an off-site meeting. May I accept the offer?

Subsidies from vendors should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses. There also should be no payment directly to a physician for attending the meeting if the physician’s participation is passive. It is appropriate for a speaker or other active conference participant to accept a reasonable honorarium and to accept reimbursement for reasonable travel, lodging, and meal expenses.

### A company has offered me a Publication Support Agreement that does not pay me or the University any money, but gives me the services of a professional writer/editor in preparing a manuscript. The company will also help me with the figures and graphs, and clearing any copyright issues. This would be really helpful to me, and I would still get the final editorial review of the manuscript. Is this permitted under the Industry Relationship Policy?

No. Publication Support Agreements are considered impermissible ghostwriting arrangements under the Industry Relationship Policy.



## Under what circumstances can I accept payment directly from Industry for speaking engagements conducted outside of the University of Pittsburgh and UPMC?

These types of activities fall under the guidelines and approval processes for consulting at the University of Pittsburgh and UPMC, including the consummation of a written agreement that is compliant with provisions in Section 6 of the Industry Relationships Policy and which is executed prior to the engagement. In addition to the limit of the honorarium to \$2500, compensation for travel expenses must be reasonable (consistent with the duration and nature of the speaking engagement and in compliance with UPMC and/or University of Pittsburgh travel policies). For example, Industry cannot compensate for extra nights' lodging beyond what would be required to conduct the speaking engagement, and payment for international travel for brief speaking engagements would not be considered reasonable.

In addition, the event itself must be an acceptable event under the Industry Relations Policy. In general, professional society sponsored scientific or clinical programs where CME is awarded and the content is not controlled by industry sponsors are acceptable. However, "satellite symposia" where a specific company sponsor is paying for the event and has oversight of the faculty member's content and/or introduces a promotional component to the program through the content of the other speakers is not an acceptable speaking venue for our faculty.

## A device, biologic, and/or drug manufacturer would like to conduct a training session using the company's product(s) in our animal facilities. Is this permissible, and what approvals are needed?

In general, company-sponsored, product-specific training in University or UPMC facilities is not permitted under the Industry Relationship Policy. In particular, use of animals for product demonstration or product training would not be acceptable under University IACUC policies. Where UPMC has already approved a particular device through its Value Analysis Program, and that device is in use in clinical settings, training of residents and staff on its use should be conducted by UPMC physicians in that setting.

If UPMC or University personnel wish to design and control their own training course, and if an animal model is absolutely the only way to accomplish this training, and the training is capable of and necessary to correct identified and quantified serious safety issues with the particular procedures or products in question, such a course may be approvable. In this latter case, Industry support may be allowable, subject to an appropriate agreement being negotiated through the University with the funding source.

Agreements that seek to lease or rent the University facilities, or which permit instruction by Industry representatives, or which include third parties invited by Industry representatives, will not be approved.

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# Speaking Engagements and Attending Industry Functions

My spouse (who does not work at the University or UPMC) has been invited to a dinner funded by a drug manufacturer; may I accompany my spouse to this event?

Yes, provided that you pay for your own meal. Although the invitation is to your spouse, the same principles that apply to the direct prohibition of Industry providing you with gifts or free meals would apply in this case.

I have been asked to speak at an event for which Industry is providing sponsorship; are there any limitations in the policy on my accepting this invitation?

Faculty may participate as speakers at Industry-sponsored educational meetings, but both the event and the lecture must meet the requirements of the policy as described in Section 6 of the IR Policy). As for the event, it should be an activity that is designed to promote evidence-based clinical care and/or to advance scientific research; the financial support of Industry must be disclosed; Industry must not pay attendees' travel and attendance expenses, or provide gifts or other compensation for attendance; and any meals provided must be modest (i.e., the value of which is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service).

If the event meets these requirements, faculty members may participate as speakers, provided that they prepare their own content (i.e., have full control of their content without any approval of the content by Industry), and the talk reflects a balanced assessment of current science and alternative treatment options and is not focused on a single company's product. The speaker must make it clear that the views expressed are those of the speaker and not of the SOHS. Faculty members may accept a modest honorarium (not to exceed \$2,500 per event) and reimbursement of reasonable travel expenses.

Please note that reimbursement of travel expenses for speakers is a part of the compensation that faculty receive for speaking, and, therefore, reimbursement of travel expenses for speakers—so long as Industry does not pay the travel expenses of those who are simply attendees—does not violate the policy. Department chairs must verify that the off-campus activity meets these requirements before approving the speaking agreement.

I have been invited to an event to announce a new product launch by a drug or device company; is this permitted? What if I am invited to participate as a speaker?

No. Such an event would not be designed to promote evidence-based clinical care; it would be a promotional event for one company's product. Because the event is promotional, attendance as a speaker would not be appropriate.

If I am asked to speak at a meeting, how do I differentiate between a venue that is permitted under the policy (one that promotes evidence-based clinical care and/or advances scientific research) and one that is not permitted (e.g., a marketing or advertising event)?

This [checklist](#) (developed by WPIC) can be used as an example to help you assess whether or not a particular event is designed for marketing or advertising purposes. The single most significant indicator of whether an event is designed for marketing is whether the company seeks to provide you with the content to deliver or seeks to approve or edit your materials.

Commercial interests cannot exert control over the content of your presentation, including mandating that you use materials that they produce, and/or requiring that they review and approve your content. Meeting attendees cannot have travel or lodging paid by the company (unless participation in the meeting is part of a training program paid for under an equipment purchasing agreement) and cannot accept personal gifts, compensation for attending, or meals that exceed the IRS standard meal allowance, or occur apart from the educational activity.

The intent of the activity must be balanced and educational in nature. Dinner meetings at expensive restaurants, where the talk is a minor part of the event, would be considered primarily promotional. Programs designed to advertise or promote a specific product without providing risks, contra-indications, and unbiased information about competitors' products are not programs at which UPMC personnel or University faculty should speak.

**A company has invited a faculty member to speak at an event next week; is there a simple, quick way to ensure that the speaking agreement with Industry complies with the requirements of the Industry Relationship Policy?**

You should first ensure that the speaking engagement is for an acceptable event (i.e., it will promote evidence-based clinical care or advance scientific research). That being the case, instead of editing an Industry-proposed agreement, both parties should sign and date the [Speaker's Agreement Addendum](#) to override impermissible terms of the Industry-proposed agreement.

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# Consulting

## What are the guidelines for obtaining legal/business reviews and approval for consulting agreements under the new policy?

Before submitting a consulting or speaking agreement for review, a faculty member or UPMC physician should first verify that the proposed agreement meets [Guidelines for Contracting with Outside Industry](#) (which can be shared with the outside company requesting consulting services). The Guidelines include specific requirements for a detailed description of services to be provided, along with details of the proposed compensation and expected maximum time commitment. Some proposed services are never appropriate for consulting arrangements, such as changes in the physician's prescribing practices and promotional and marketing activities.

Please consult the [Consulting section](#) of the University's COI website for information on reviews of proposed consulting agreements for University-only, UPMC-only, and personnel holding dual appointments with the University and UPMC or University of Pittsburgh Physicians (UPP).

## For PhD researchers consulting with Industry, will the consulting approval processes apply, or is this applicable only to physicians making clinical decisions?

The consulting approval process applies to all faculty members in the Schools of the Health Sciences.

Please consult the [Consulting section](#) of the University's COI website for information on reviews of proposed consulting agreements for University-only, UPMC-only, and personnel holding dual appointments with the University and UPMC or University of Pittsburgh Physicians (UPP).

## I have been asked to host visiting physicians in the UPMC operating room who are interested in learning how to use a particular vendor's equipment in patient care. Does this policy permit me to receive a consulting fee for such an event?

No. Consistent with UPMC Conflict of Interest Policy No. HS-LE0002 and University Policy [02-06-01](#), Outside Employment, employees cannot use UPMC or University resources to generate personal income/revenue. Moreover, UPMC tax-exempt facilities cannot be used by for-profit entities for marketing activities. For acceptable models for CME sponsorship, see UPMC Section IV, 5 or SOHS Section C, 5 of the Policy.

## What are the procedures for review of proposed faculty or UPMC employee consulting agreements?

Please consult the [Consulting section](#) of the University's COI website for information on reviews of proposed consulting agreements for University-only, UPMC-only, and personnel holding dual appointments with the University and UPMC or University of Pittsburgh Physicians (UPP).