

## INDUSTRY RELATIONSHIP POLICY GUIDANCE:

### How to bring your agreement into compliance

The following materials have been developed to facilitate relationships between the employees of UPMC and/or the faculty of the University of Pittsburgh Schools of the Health Sciences (SOHS) and Industry<sup>1</sup> that are free from bias or the perception of bias by ensuring that the terms of consulting and non-disclosure agreements between UPMC providers or staff, SOHS faculty, personnel, or students and external organizations are consistent with all of the applicable UPMC and University of Pittsburgh (UNIVERSITY) policies, including COI<sup>2</sup> policies. This document should be used by both Industry and UPMC/UNIVERSITY staff to bring an agreement into compliance.

#### Does my activity require an agreement<sup>3</sup>?

If you are interacting with Industry and, as a result of your participation/services, you will receive remuneration or reimbursement of any kind, a written agreement is required that at minimum:

- Clearly and explicitly describes the services to be performed;
- Ties compensation directly to the services at a per hour or per service rate; and
- Acknowledges the elements listed below.

In addition, please note that an even if work is unpaid, an agreement may still be required. Check with the University's COI Office (Pitt-only faculty) or the UPMC Ethics and Compliance Office (dually-employed faculty physicians and UPMC-only employees).

#### When entering into a relationship with Industry the following elements must be addressed in the agreement:

- 1. Prohibitions regarding Marketing, Promotional, and Sales Activity.** UPMC and UNIVERSITY recognize the importance of sharing their employees' scientific expertise with Industry; however, they may not participate, directly or indirectly, in marketing, promotional, or sales activity on behalf of Industry. The expertise provided to companies should be focused on the scientific improvement of the product or procedure (not on how to better market, sell, or promote them). The services to be provided must be described fully, whether in the body of the agreement or in separate addenda.

If a consultant is speaking or giving a presentation at an Industry-sponsored meeting, the consultant can present only materials that promote evidence-based clinical care or scientific research. The consultant must control the final content of the presentation, and the content may not be subject to approval by the Industry-sponsor beyond what is required to meet FDA requirements, should they apply. Participation in promotional speaker's bureaus is prohibited. Participation in "satellite symposia" sponsored by Industry as an adjunct to professional meetings is prohibited.

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<sup>1</sup> For purposes of this policy, "Industry" is defined as all pharmaceutical manufacturers, and biotechnology, medical device, and hospital equipment supply industry entities and their representatives. "Nutraceutical" companies including but not limited to vitamin and supplement companies are also subject to University/UPMC policies. Also, CME activities need to be carefully evaluated to determine the level of Industry influence.

<sup>2</sup> "A conflict of interest is a set of circumstances that create a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." (*Institute of Medicine*. "Conflict of Interest in Medical Research, Education and Practice." 4/21/2009). UPMC and University of Pittsburgh manage potential conflicts of interest by prospectively reviewing all outside activities of employees and faculty.

<sup>3</sup> If an outside activity does not require a written agreement because there is no interaction with "Industry" as defined herein, it is still subject to other applicable UNIVERSITY and UPMC policies including but not limited to UPMC HS-EC 1700 Conflicts of Interest-General Obligations and the University Policy [02-06-01](#) *Outside Employment*.

Examples of Acceptable Contract Language:

- “Consultant will provide support to ABC Company clinical trial on Product A1. A1 is the subject of a principal open label study to compare brain uptake of XYZ with other brain levels determined post-mortem.”
- “Consultant will become a member of ABC Company’s advisory board where advice will be provided on the Company’s research and development of: (i) Product X and (ii) Product Y.”
- “Consultant will develop educational materials on Disease X and deliver 3 presentations to research and development staff. Consultant will have full editorial control of the content of the presentation.”

Examples of Unacceptable Language:

- “As part of an advisory board, Consultant will discuss current or potential marketing and/or sales of Product XYZ.”
- “Consultant will perform, from time to time, consulting services for ABC Company.”
- “Consultant will be provided with (a slide deck, materials, etc.) for use in the presentation, and under no circumstances may Consultant edit the materials without the approval of Company.”
- “Consultant will assist in negotiations for the distribution of Product XYZ by serving as technical liaison between Company and potential buyers, and by offering technical assistance with marketing when requested.”
- “Consultant will review Product XYZ advertising materials.”
- “Consultant will make presentations at ABC Company sales/marketing meetings.”
- “Consultant will review market and competitive trends/data.”

2. **UPMC and UNIVERSITY are not parties to personal consulting agreements.** Neither organization has any obligations or potential liability under any personal consulting agreement between their employees and Industry, nor are their respective rights impaired in any way by such agreements. Institutional representatives of UPMC and UNIVERSITY do not sign personal consulting agreements for any reason. In addition, UPMC/UNIVERSITY do not provide indemnity or professional liability insurance to their faculty/staff for outside consulting activities.
3. **Use of UPMC and UNIVERSITY name and affiliation.** Faculty/employees cannot publicize their affiliation with UPMC or UNIVERSITY in any manner that states or implies that the consulting work is being performed in their professional capacity at UPMC/UNIVERSITY, or that the Company’s products or activities are being endorsed by UPMC/UNIVERSITY. In addition, the UPMC/UNIVERSITY logos should not be used in the consulting activities. Faculty/employees should be clear that advice or opinions given in the performance of consulting services are not given in the consultants’ role as employees of UPMC/UNIVERSITY. Consultants must use their personal/home address in consulting agreements, as opposed to their UPMC/UNIVERSITY address. Requests by Industry to videotape, record, or otherwise use the likeness of a faculty/employee must be reviewed to ensure that the proposed use will not be for a marketing or promotional purpose.

Unacceptable Language:

- “Consultant, a physician at UPMC, will perform speaking services on behalf of Company on Disease ABC.”

4. **Ownership of Intellectual Property.** UPMC/UNIVERSITY policies retain intellectual property (IP) rights of their employees/faculty under the terms described in their respective Patent and Copyright Policies. Because of the intellectual property rights previously granted by the employees/faculty to

UPMC/UNIVERSITY, employees/faculty may not assign any rights in IP resulting from the consulting work without the express written consent of UPMC/UNIVERSITY. To avoid the burden and delay of assessing every potential engagement for IP, consulting agreements that contain an assignment of IP rights must either delete the assignment language or revise the assignment language to acknowledge the superior rights that both UPMC and the UNIVERSITY have in the IP under their Patent and Copyright policies before the physician executes the agreement. If no IP is expected to be generated as a result of the consulting relationship, the agreement can remain silent on the issue, provided however that the consultant discloses that he/she has prior obligations with respect to any IP he/she may develop under agreement.

Acceptable Language:

- “Company and Physician agree and acknowledge that any assignment of intellectual property rights contemplated under this Agreement shall be subject to the superior rights of UNIVERSITY and of UPMC under their respective intellectual property and patent policies. Only if UNIVERSITY and UPMC first waive such rights in writing may Physician assign intellectual property rights to Company.”
- “The parties agree to remain silent with respect to intellectual property, but Company is aware of the Consultant’s existing obligations to the University of Pittsburgh/UPMC with respect to any intellectual property that consultant may develop hereunder.”
- “Company and Consultant agree and acknowledge that any assignment of intellectual property rights contemplated under this Agreement shall be subject to the superior rights of UNIVERSITY and of UPMC under their respective intellectual property and patent policies. To the extent permissible by the policies, and only if the University and UPMC in writing waive any right they may have, the Consultant agrees to assign (or cause to be assigned) fully to the Company all such inventions and any copyrights, patents, or other intellectual property relating thereto. The Consultant agrees to take prompt steps to seek a written waiver from the UNIVERSITY and/or UPMC of any rights those entities may have in any intellectual property, and to keep the Company apprised of the status of such requests.”

Unacceptable Language:

- Any language that does not acknowledge the superior rights of UPMC and/or UNIVERSITY as outlined above.

5. **Compensation.** Compensation must be reasonable and commensurate with the services to be provided. The deliverables and time commitment must be explicitly detailed. The compensation must be directly tied to the services provided. While stock options or other forms of equity may be provided as compensation for services, the equity may only transfer or vest upon the performance of the services.

Compensation for speaking services is limited to \$2,500 (Two thousand five hundred) per speaking event. Compensation for consulting services is limited to no more than \$500 (five hundred) per hour. Receiving royalties as compensation for consulting services is generally prohibited for healthcare providers<sup>4</sup>. Commission resulting from the sale of goods as compensation is also generally prohibited.

For University faculty, the approval of the Senior Vice Chancellor for the Health Sciences, Dr. Arthur S. Levine, and a conflict management plan are required if any of the following conditions apply:

- total compensation under the agreement exceeds \$10,000 during any 12 month period;
- stock/stock options in a **private** company are offered as compensation;

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<sup>4</sup> Providers are physicians or other medical professionals with the authority to order prescriptions, medical devices, etc.

- stock/stock options in a **public** company that exceed 5% ownership interest in the company or \$10,000 in value are offered as compensation;
- or other scenarios that may require management of potential conflicts of interest.

Faculty can choose to cap the compensation in the agreement at \$10,000 in any 12 month period to eliminate the need for Dr. Levine's approval and a conflict management plan.

Acceptable Language:

- "Company will pay Consultant \$250/hr. to give advice on prosthetic devices at two 4-hour meetings a year."
- "Consultant will be paid \$250/hr. up to a cap of \$1,200/year for reviewing 12 samples....."
- "Physician will be available for up to 12 one-hour phone meetings per year to discuss vaccine advances and will be paid 15 shares of company stock valued at \$16 per share for each meeting."

Unacceptable Language:

- "Consultant will receive 500 stock options upon signing the consulting agreement with Company and quarterly thereafter."
- "Each attendee and spouse at our scientific conference will have all expenses paid at World's Best Luxury Resort where new products will be unveiled."
- "You will be paid \$5,000 to identify experts in the field and will receive an additional 2.5% of the gross profit of project fees if all recruitment goals are met."
- "Consultant will receive \$3,000 every quarter for availability/participation/services for Company's advisory board/speaking/research and development."

- 6. Primary Employment.** Nothing in any consulting agreement should be interpreted in any way to restrict UPMC/UNIVERSITY staff in their primary obligations to UPMC and UNIVERSITY or from engaging in other research activities at UNIVERSITY/UPMC sponsored by another company.

Unacceptable Language:

- "While performing the services under this Agreement, Consultant may not engage in additional research opportunities without approval from Company."
- "Consultant may not disclose the terms of this Agreement to his/her employer without prior consent of Company."

- 7. UPMC and UNIVERSITY resources and facilities should NOT be used in the performance of personal consulting services.** No UPMC or UNIVERSITY resources (e.g., support staff; facilities; equipment; personal computers; software; staff) can be used to generate personal income under the Agreement. Faculty/employees should not host business meetings related to outside professional activities with Industry personnel or other medical professionals in UPMC/UNIVERSITY facilities. UNIVERSITY and UPMC administrative staff should not be used to facilitate travel arrangements or provide other support services related to a faculty member/employee's consulting work.

Unacceptable Language:

- "Consultant will perform the services at UPMC/UNIVERSITY/Consultant's Institution."

**Please note the following activities are prohibited:**

- **Confidential Information.** Confidential Information acquired through UPMC/UNIVERSITY business or research activities may not be used for personal gain, or to grant unauthorized access to others. Confidential information is defined as any information that comes into your possession as a result of your employment by UPMC/UNIVERSITY that is not broadly available to the general public. This includes unpublished results of research.
- **Industry-Sponsored Training.** Industry cannot provide pay for travel to Company-sponsored training unless the individual is a trainee and UPMC has already entered into a purchase contract for the device/drug for which the training is offered. In that event, the company training must be addressed as part of the purchase agreement with UPMC, and UPMC will determine who will attend.
- **Full-time Faculty and Employees are generally not permitted to serve as officers of a company as part of a consulting relationship.** An “officer” is defined as a high-level management official of a corporation or an unincorporated business who has fiduciary obligations to the business. Examples include president, vice president, secretary, financial officer, chief scientific officer, chief medical officer, chief technology officer, or chief executive officer.
- **Consulting for Hedge/Investment Funds/Venture Capitalists.** This practice is strongly cautioned against. For more information, please see: <http://www.coi.pitt.edu/Resources/InvestmentAnalysts.pdf>
- **Research.** Research may not be conducted under a personal consulting agreement. Any activity that involves access to Protected Health Information (PHI) is inappropriate, as it would constitute an engagement in research. Such work should be conducted through an institutional research agreement between UPMC/UNIVERSITY and the Company, not as personal consulting. Contact the University Office of Research or the UPMC Office of Sponsored Programs and Support, as appropriate, to arrange an institutional funding agreement.
- **Site Access by Sales and Marketing Representatives.** Sales and marketing representatives are not permitted in any patient care areas, except by appointment, to provide approved in-service training on devices and other equipment.

**Other Notes:**

**Expert Witness Consulting Services.** UPMC PSD staff performing services as a legal consultant or expert witness are subject to the *Medicolegal Evaluations and Testimony Policy (PSD-ADM-007)*. This policy should be consulted PRIOR to performing medicolegal services to ensure compliance.