

# **Supplemental Rule 1-006: Health Sciences Industry Relations Policy**

## **Effective December 1, 2015**

### **I. Purpose**

The University of Utah Health Sciences (“UUHS”) is committed to outstanding education, research, and patient care that are free from inappropriate external influences. We recognize the important partnership between industry and academia in advancing all of these missions. The purpose of this Policy is to set standards of education and interaction between UUHS faculty, staff, and trainees and industry entities or representatives. Conflict of interest issues regarding research, human subjects, and the interaction between industry and University of Utah Hospitals and Clinics (“UUHC”) personnel are addressed in separate policies.

### **II. Definitions**

- A. **Business Entity:** “Business Entity” means a sole proprietorship, partnership, association, joint venture, corporation, limited liability company, firm, trust, foundation, or other organization or entity used in carrying on a trade or business.
- B. **Consulting:** “Consulting” shall mean any relationship where a University employee is retained by an industry business entity to provide professional advice or services outside of their University employment.
- C. **Faculty:** “Faculty” shall include all full- and part-time faculty with tenure-line or career-line (clinical, research, or lecturer) faculty appointments. The term also includes faculty with adjunct appointments, whether paid or unpaid, whenever they are acting in their capacity as a UUHS faculty member (such as interacting

with trainees, representing themselves as faculty members, and/or working as a health care provider for UUHS).

- D. **Family:** “Family” shall include spouse/domestic partner and/or dependent children.
- E. **Gifts:** “Gifts” shall include money, food, any other non-pecuniary item (e.g., entertainment, flowers, notepads, pens, etc.), excessive compensation, and non-commercial loans.
- F. **Industry:** “Industry” shall refer to all persons and business entities that do business, or may do business, with UUHS, including all pharmaceutical manufacturers, and all biotechnology, medical device, hospital equipment, and service supply industry entities and their representatives.
- G. **Intellectual Property:** “Intellectual Property” shall mean any ideas, inventions, technology, creative expression, and embodiments thereof, in which a proprietary interest may be claimed, including, but not limited to, patents, copyrights, trademarks, know-how, and biological materials.
- H. **Financial Relationships:** “Financial Relationships” shall mean any financial interest or relationship that reasonably relates to an individual’s responsibilities to the University, as defined by an individual’s department or job description, and shall include any of the following:
  - 1. Employment, consulting, and any other activity resulting in payment to an individual (including gifts, royalties, travel).
  - 2. Any equity ownership interests (e.g., stock, partnership interest, member interest) in an industry business entity, excluding ownership in mutual funds and/or pension funds.
  - 3. Any leadership position (e.g., officer, director, partner).
  - 4. Any intellectual property ownership (e.g., patents, copyrights, trademarks).

- I. **Manager:** “Manager” shall mean any UUHS staff employee employed at the manager level or above.
- J. **University of Utah Health Care/UUHC:** “University of Utah Health Care” and/or “UUHC” shall include all health care delivery and educational programs of the University of Utah, to include hospitals, clinics, centers, teaching locations, and providers.
- K. **University of Utah Health Sciences (“UUHS”):** “UUHS” shall include all academic units within the University of Utah Health Sciences, including, but not limited to, the School of Medicine, the College of Nursing, the College of Health, the College of Pharmacy, the School of Dentistry, and the Spence S. Eccles Health Sciences Library.

### III. Policies

#### A. Industry Representative Visits, Materials and Samples

- 1. **Industry Representative Appointments and Identification:** The following policies apply to all areas of UUHS, except when exclusively related to existing equipment, supplies, technical support, or training for laboratory research.
  - a. **Appointments.** All industry representatives are required to have an appointment. “Cold calling” is prohibited. Pharmacy and Support Services may verify industry representative appointments. Industry representatives without an appointment will be turned away or given the opportunity to call and make an appointment. Faculty and staff are asked to report industry representatives who make sales calls to their areas without an appointment or vendor pass. UUHS Faculty and staff should not meet with pharmaceutical and medical device representatives except by a documented appointment and at the Faculty/staff member’s expressed invitation. The purpose of such meetings should generally be for education, research, patient safety, or the evaluation of medical devices.



- useful to our patients. All materials distributed in UUHC clinical sites must also comply with UUHC policies (UUHC Vendor Gifts Policy and Other Vendor Policies).
4. **Public Areas.** All public areas, including Faculty, staff, and trainee lounges, in UUHS must be free of any materials that bear the name of a particular product or company. See also UUHC Vendor Gifts Policy and Other Vendor Policies.
  5. **Samples.** UUHC does not allow industry samples within the organization unless the use of such samples is approved through the Pharmacy & Therapeutics Committee. Before providing drug samples or medical surgical supplies to UUHC or UUHS Faculty, employees, or trainees, industry representatives must check with Service Directors to assure the existence of, and compliance with, approved UUHC protocols. Similar approval processes should apply to non-UUHC practice and teaching locations. All sample distribution must have the approval of the department chair (or designee) or dean (or designee).
  6. **Other Industry Representative Policies.** All UUHC policies regarding industry representatives also apply to UUHS locations, Faculty, staff, and students (UUHC Policy on Conflicts of Interest Issues for University Hospitals & Clinics, UUHC Vendor Gifts Policy and Other Vendor Policies).

## B. Gifts From Industry Representatives

1. **Gifts to individuals.** Utah law and University of Utah policy prohibit employees from receiving gifts that may improperly influence employees in the conduct of their responsibilities (Utah Public Officers' and Employees' Ethics Act, Utah Code Ann § 67-16-1 et seq., Policy 1-006, Conflict of Interest Policy). UUHS prohibits industry representatives from giving gifts of any kind to UUHS Faculty, staff, or trainees. UUHS Faculty, staff, and trainees are

prohibited from accepting gifts of any kind from industry representatives. More specifically:

- a. Individual industry representatives are not allowed to bring food into the organization.
- b. Faculty/Staff/Trainees are not allowed to have meals paid for by industry representatives, except in circumstances described elsewhere in this Policy.
- c. Faculty/Staff/Trainees are not allowed to receive gifts, regardless of value and regardless of where the gifts are given (e.g., within UUHS facilities, within physician offices, at conferences, etc.)

2. **Gifts to Departments, Divisions, and Programs.** Except as specifically provided below, industry representatives are prohibited from providing gifts to individual departments, divisions, and programs. This prohibition applies to educational events, but also to other professional activities such as administrative, academic, or clinical meetings, sales calls, employee or patient social events, staff planning sessions, or retreats.

- a. **Continuing Education Donations.** Industry representatives may provide funding for educational events administered by the University of Utah Office of Continuing Medical Education (“UUCME”) or similar offices within the colleges/schools of Pharmacy, Health, Nursing, and Dentistry. UUHS events receiving industry support must, at a minimum, comply with the ACCME Standards for Commercial Support, regardless of whether continuing education credit is awarded. Commercial support shall not be conditioned on other actual or potential business relationships. UUHS schools/colleges (and other relevant offices) will maintain a record of contributions and the programs supported from the fund in accordance with the standards of industry support for continuing education.

- b. **Site Visits.** Industry representatives may fund site visits by Faculty or staff necessary for evaluating products and equipment. However, industry representatives may only pay for the reasonable and actual cost of travel, food, and lodging. A department chair (or designee) or dean (or designee) must approve site visits in advance.
  - c. **Industry-Sponsored Scholarships and Educational Funds.** Industry representatives may provide funding for scholarships and educational opportunities but only in accordance with the requirements set forth below in Section III.C. of this Policy.
  - d. **Philanthropic Gifts.** UUHS departments, divisions, and programs may receive philanthropic donations from industry or businesses as outlined in University policies. However, such funding must be arranged through a development officer in the applicable college/school and must be provided pursuant to an approved pledge agreement or gift agreement. Departments, divisions, and programs that receive such funding shall not be subject to any implicit or explicit expectation of providing something in return for the support (i.e., a quid pro quo). Moreover, the name of the University of Utah, the college, the school, the department, the division, and/or the program may not be used by the business entity to imply endorsement of a product or service by the University, the college, the school, the department, the division, or the program.
  - e. **Publisher/Distributor Books.** University Policy 6-318 shall govern the receipt of books from publishers and distributors.
3. **Incentives.** There can be no reward for prescribing any industry representative's device or medication or for referring or listening to sales promotions. Personnel may not accept payment for evaluating any health care product. Scientific studies funded by industry should be specified by a contract that contains specific deliverables and dates.

4. **Applicable Hospital Policies.** UUHS Faculty, staff, and trainees are also subject to all applicable UUHC policies regarding industry representative gifts.

C. Industry-Sponsored Scholarships and Educational Funds for Trainees

Departments, divisions, and programs may only accept industry funding for scholarships and other educational events as provided below. The funding mechanisms relevant to this Policy include grants for educational initiatives, scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training. Specifically, the industry funding must comply with all of the following:

1. Fellowships directly from industry, whether merit-based or not, must be approved by a dean (or designee) for compliance with this Policy.
2. Students and/or trainees who receive industry-sponsored scholarships or other educational funding must go through the same selection process as other students/trainees supported by UUHS school, college, departmental, division, or program funds. The department, program, or division must select the student or trainee.
3. Industry will not have any input in selection of students/trainees, except in cases of competitive industry-sponsored awards that are open to trainees of multiple institutions based on merit.
4. The funds are provided to the department, division, or program and not directly to student or trainee.
5. The department, division, or program has determined that the funded conference or program has educational merit.
6. The educational activity for which this scholarship applies must not be limited to a single industry representative's products.

7. The department, division, program, and the recipient shall not be subject to any implicit or explicit expectation of providing something in return for the support (i.e., a quid pro quo).
8. The name of the University, school, college, or department, or the attendee's affiliation, may not be used to imply endorsement of a product or service by the University, school, college, or department.
9. These provisions do not apply to educational programs for trainees at national or professional society meetings, awards, or travel grants presented by professional societies, or refereed competitive awards that are free of commercial influence.

#### D. Industry-Sponsored Non-Accredited Events

1. Attendance at meetings sponsored by industry based on relationships as expert consultants, collaborating investigators, or for education about specific products or their uses is permitted as long as attendance legitimately pertains to those activities, and as long as such meetings are not marketed or conducted as continuing education events. Such participation is permitted only if all of the conditions below are met:
  - a. The event addresses a bona fide scientific, education, or business purpose.
  - b. Participation and payment for participation must be approved by a chair (or designee) or dean (or designee) in advance.
  - c. Attendance is either for the purpose of participation as an educator, learner, investigator, or consultant in a fair and objective exchange of information, or for learning about new products or uses of products directly relevant to the participant's research or practice.

- d. Honoraria are reasonable and reimbursements limited to actual costs of travel, meals, and fees for Faculty acting as organizers, presenters, or panelists. Faculty may not accept payment for attendance only.
  - e. There can be no compensation beyond reasonable reimbursements and honoraria as defined above. Compensation in the form of gifts, event tickets, fees for social or recreational activities, or expenses at vacation resorts is prohibited.
  - f. Meals or receptions attended during such programs are modest and conducted to further the scientific, educational, or business purpose of the meeting.
2. UUHS-sponsored events must comply with the standards of industry support for continuing education programs (See Section III.B.2.a. above), even in the absence of continuing education accreditation.

#### E. Trainee Education and Expectations Regarding Professionalism

1. Educational programs will be included in the curricula for students and trainees to address the issues of professionalism and relationships with industry.
  - a. Specific educational objectives will be developed as part of these curricula.
  - b. Assessment methods for meeting the educational objectives will be part of the assessment of all students and trainees.
  - c. Existing curricula, such as that developed by the National Faculty Education Initiative ([www.nfeinitiative.org](http://www.nfeinitiative.org)), may be used to meet these educational objectives.
  - d. The content and success of these programs will be regularly reviewed and updated as part of ongoing curriculum management.

2. Unless related solely to laboratory research, students and trainees will not interact with industry representatives, unless it is in the presence of a Faculty member as part of the educational curriculum.
3. Industry support for educational activities of students and trainees is prohibited, except as expressly permitted in this document.
4. All prohibitions on food, gifts, travel, and other industry interactions addressed in this Policy also apply to students and trainees.
  - a. Prohibitions for students and trainees remain in force when students or trainees are involved in approved educational activities outside of the University of Utah.

#### F. Relationships Between Faculty and Industry

1. **Consulting.** Consulting is a legitimate and approved activity for UUHS faculty and some senior administrators. It is permissible under the following conditions:
  - a. Consultants must comply with the requirements of the University consulting policy, [Policy 5-204](#).
  - b. Faculty/administrator consulting activities are limited to the amount of time specified in University Policy [5-204](#) and must not interfere with University responsibilities.
  - c. Payment must be at fair market value for time given in consultative work that constitutes provision of genuine expertise.
    - i. Consulting arrangements must be approved by a department chair (or designee) or dean (or designee) in advance.

- ii. A decision to reject a consulting arrangement may be appealed to a dean (or to the Senior Vice President of Health Sciences in the case of a dean).
- d. Consulting arrangements of UUHS administrators (chairs, division chiefs, etc.) must be approved by the next level supervisor. Consulting arrangements of the Senior Vice President of Health Sciences must be approved by the President of the University.
- e. Consulting activities require a formal contract between the company and the University of Utah personnel that specifies legitimate tasks and deliverables.
- f. Compensation and reimbursement must comply with the requirements outlined in section III.D. above. Honoraria must be reasonable and reimbursements limited to actual costs of travel, meals, and fees for Faculty consultation.
- g. Payment cannot include gifts, entertainment, or other perquisites. Payments cannot involve kickbacks or direct payments that might influence use of the company's product.
- h. Consultation cannot consist of participation in marketing surveys, product promotion, token advisory relationships, or presentations using instructional content from the industry sponsor.
- i. Activities related to development of intellectual property must adhere to University and UUHS policies for intellectual property and commercialization.
- j. When Faculty members consult on projects involving human subjects research, they should confirm that the research has been, or will be, approved by an appropriate institutional review board.

- k. Presentation of data derived from consultation activities must be peer reviewed or limited to research meeting with peers.
2. **Financial Relationships:** Faculty and Managers (and their Family) may have Financial Relationships with business entities. Where such relationships exist, Faculty and Managers must comply with the following requirements:
- a. The Financial Relationships of a Faculty member/Manager and his/her Family must be reported to, and approved annually by, the individual's chair (or dean if the chair is similarly conflicted).
  - b. Faculty/Managers whose Financial Relationships include the performance of services for the business entity must comply with the requirements of the University consulting policy, [Policy 5-204](#), and the consulting provision of this Policy, Section III.F.
  - c. Faculty/Managers involved in University research, purchasing decisions, or intellectual property transfers relating to the industry business entity shall comply with the University's Conflict of Interest Policy, [Policy 1-006](#), including reporting of the conflict and compliance with any management plan.
  - d. Faculty/Managers involved in purchasing decisions relating to the industry business entity shall also comply with the UUHC Conflict of Interest Policy.
  - e. To the extent the Financial Relationship includes an intellectual property ownership in the products of the industry business entity, Faculty cannot receive royalties for use of products in their own clinical practice.
  - f. Faculty/Managers conducting research for the industry business entity at the University must refrain from transferring any materials (DNA, plasma, biological specimens, micro arrays, instrumentation, etc.) obtained or developed in the course of research in this setting to the business entity except as outlined in University policy.

### 3. Industry Research Support

- a. Industry-academic collaboration is usually necessary to bring drugs, devices, and other technologies to fruition.
- b. Industry-academic collaboration in the form of industry-sponsored research may give rise to conflicts of interest when Faculty or staff have an external financial relationship with the industry sponsor. These relationships require reporting and management in compliance with the University's conflict of interest policy, [Policy 1-006](#). The conflict management process ensures transparency of all financial conflicts, adherence to ethical research principles, and compliance with applicable state and federal law. The Institutional Review Board ("IRB") and the Office of Sponsored Projects ("OSP") assist Faculty in documenting their compliance with applicable University policy during the IRB review and research grant contracting processes to maintain transparency.
- c. Faculty financial conflict management relating to research support must comply with applicable state and federal law. Faculty and staff must also comply with the "no gift" expectations of this Policy when interacting with industry research collaborators.

### 4. Speakers Bureaus

- a. Presentation that promote a vendor, a product, or a service are prohibited by this policy.
- b. Serving on speakers' bureaus or speaking with industry support is strongly discouraged.
- c. Participation on speakers' bureaus is permitted only if presentations are unbiased and do not promote a product/service of the sponsor. This would include meeting all of the following conditions:

- i. Participants must comply with the requirements of the University consulting policy, [Policy 5-204](#), and the consulting provision of this Policy, Section III.F.
  - ii. Presentations must comply with all applicable FDA regulations.
  - iii. Participation and payment for participation must be approved by a department chair (or designee) or dean (or designee) in advance.
  - iv. Industry support must comply with the commercial support standards for the relevant continuing education accrediting bodies (e.g., the ACCME Standards for Commercial Support ([www.accme.org](http://www.accme.org))).
  - v. Payment is at fair market value for work done, including preparation of presentations. Payment cannot include gifts, entertainment, or other perquisites of any kind.
  - vi. Financial support is fully disclosed to the audience.
  - vii. Presenters are solely responsible for presentation content, do not use industry-provided educational materials, and are responsible for evidence-based and objective presentation of information.
  - viii. Industry support for Faculty participation is not contingent upon any other relationship or agreement between the industry supporter and the presentation organizer.
- d. Industry support for non-promotional community education programs is permissible.

## 5. Ghostwriting

- a. The University expressly prohibits the practice of “ghostwriting” wherein an industry representative writes a scientific manuscript, in whole or in part, and credits, in whole or in part, University Faculty and/or staff who did not

participate in writing the manuscript. Faculty and staff who publish articles with industry representatives must participate in the preparation of the manuscript in a meaningful way to include interpretation of data and/or the writing of the manuscript and shall be listed as authors or otherwise appropriately cited for their contribution. Faculty and staff who collaborate with industry representatives in writing scientific manuscripts must attest to the validity and integrity of the manuscript's data presentation and conclusions. The financial interests of all authors shall be listed in accordance with recognized standards of conflict disclosure.

- b. This policy banning "ghostwriting" is not intended to prohibit the collaboration of industry scientists in the production of a scientific manuscript. As set forth in University contract research agreements, representatives of the sponsoring entity have the right to review and comment on manuscripts relating to research projects they have funded, although University Faculty and staff maintain complete editorial control of the final manuscript and retain the right to publish.
- c. Faculty are discouraged from publishing research in non-peer-reviewed promotional journals.

#### G. Oversight, Noncompliance and Enforcement

1. **Senior Vice President and Dean Oversight.** The Senior Vice President for Health Sciences and the deans for the colleges and schools within UUHS shall have oversight responsibility for this Policy. The Senior Vice President for Health Sciences and the deans shall periodically review chair (or designee) decisions under this Policy to assure a reasonable level of consistency and integrity in the application of this Policy.
2. **Industry Representative Non-Compliance.** UUHS faculty, trainees, and staff shall report noncompliance by industry representatives with this Policy to the appropriate office/department.

- a. The UUHC Purchasing Office will take action when violations are reported to that department. Pharmacy is responsible for enforcing this Policy with pharmacy industry representatives. Actions taken when industry representatives do not comply with policy can include any of the following actions:
    - i. Industry representative notified.
    - ii. Industry representative's manager or other company representative notified.
    - iii. Temporary or permanent restrictions on hospital visitation privileges.
    - iv. Termination of future business.
3. **Employee and Student Non-Compliance.** Suspected violations of this Policy by UUHS Faculty, staff, or trainees will be referred to the individual's dean and/or department chair, who shall determine what actions, if any, shall be taken. Violations of this Policy may result in various levels of sanction, including but not restricted to reprimands, fines, probation, suspension, and/or dismissal pursuant to (1) the Code of Faculty Rights and Responsibilities, [Policy 6-316](#); (2) staff disciplinary policies and procedures, [Policy 5-111](#); and (3) the Code of Student Rights and Responsibilities, [Policy 6-400](#).

#### IV. References

- A. University of Utah Regulations Library, [Policy 1-006](#), Conflict of Interest Policy
- B. University of Utah Regulations Library, [Policy 5-204](#), Remunerative Consultation and Other Employment Activities
- C. University of Utah Regulations Library, [Policy 4-005](#), Use and Security of Property

- D. University of Utah Regulations Library, [Policy 5-111](#), Corrective Action and Termination Policy for Staff Employees
- E. University of Utah Regulations Library, [Policy 6-316](#), Code of Faculty Rights and Responsibilities
- F. University of Utah Regulations Library, [Policy 6-318](#), Acquisition and Control of Non-Library Books
- G. University of Utah Regulations Library, [Policy 6-400](#), Code of Student Rights and Responsibilities
- H. University Regulations Library, [Policy 7-002](#), Patents and Inventions
- I. University of Utah Regulations Library, [Policy 7-004](#), University Faculty Profit-Making Corporations
- J. UUHC Policy on Conflicts of Interest Issues for University Hospitals & Clinics
- K. UUHC Vendor Gifts Policy and Other Vendor Policies
- L. UUHC Policy on Information Confidentiality and Security
- M. Utah Public Officers' and Employees' Ethics Act, Utah Code Ann § 67-16-1 et seq.

## **V. Contacts**

Rule Officer: Senior Vice President for Health Sciences (801) 581-7480

Rule Owners: School of Medicine Dean (801) 581-6436

College of Health Dean (801) 581-8537

College of Nursing Dean (801) 581-3414

College of Pharmacy Dean (801) 581-3716

School of Dentistry Dean (801) 581-8951

Spence S. Eccles Health Sciences Library Director (801) 581-8771

## **VI. History**

This Policy was first adopted by the Executive Committee of the College Council, University of Utah School of Medicine on August 10, 2010. The Policy was subsequently expanded to cover all of the academic units within UUHS. The expanded Policy was adopted by each unit on the following dates: UUHS Library Faculty, October 8, 2013; College of Nursing Faculty, November 8, 2013; College of Health Faculty, November 19, 2013; College of Pharmacy Faculty, November 19, 2013; and School of Dentistry Faculty, April 3, 2014. It was then adopted by the Health Sciences Executive Committee on September 15, 2015, and by the University's Individual Conflict of Interest Committee in November, 2015.