

## Policy on Interactions between Clinical Personnel of Yale Medicine and Industry

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### **I. Introduction**

Yale Medicine (YM) strives to provide the highest quality health care to its patients. Through its clinical activity, YM also supports the medical education, training, and clinical research missions of the Yale School of Medicine (YSM). In some cases, interactions between YM clinicians and industry<sup>1</sup> can promote these missions and have a positive impact on patient care. Indeed, Yale University encourages its faculty “to consult widely, and to engage in other activities that may benefit not only the participants but also the University itself, and the larger public.”<sup>2</sup> These interactions with industry, however, must adhere to the highest ethical and professional standards and must be intended and designed to enhance patient care, to improve the practice of medicine, or to support medical education.

The purpose of this Policy is to increase the awareness of YM clinicians about the potential for conflicts of interest arising from relationships with industry and to establish parameters for these relationships so that actual or potential conflicts may be avoided or properly managed.

### **II. Policy Statement**

It is the policy of Yale Medicine to promote principled interactions with industry that support the clinical and educational missions of the School of Medicine and to protect these missions from interactions that create actual or perceived conflicts of interest. The complexities of relationships with industry preclude YM from identifying all circumstances in which a conflict of interest may arise or in which an interaction may be inappropriate. The principles outlined in this Policy should guide all relationships or interactions between YM clinicians and industry. For additional guidance or clarification on this Policy, YM clinicians should consult with their Department Chair or Section Chief, or with the YM Chief Medical Officer.

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<sup>1</sup> In this Policy, the term “industry” means biomedical, pharmaceutical, and medical device companies and any other companies that make products used in the treatment of patients or the provision of medical care.

<sup>2</sup> Yale University Policy on Conflict of Interest and Conflict of Commitment, May 2004, <http://provost.yale.edu/conflict-policy>.

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**III. Scope of the Policy**

- a. This Policy applies to all physicians, PAs, APRNs, RN's, midwives, or other clinicians who practice in Yale Medicine (hereinafter "Clinical Personnel").
- b. This Policy supplements the University's policies on conflict of interest. While this Policy addresses many aspects of industry relationships, Clinical Personnel are expected to comply with all other University policies and principles relating to interactions with industry including, but not limited to:
  - i. [University Policy on Conflict of Interest and Conflict of Commitment](#);
  - ii. [Policy 2201: Gifts from External Parties to Employees](#);
  - iii. [Policy 3201: General Purchasing](#);
  - iv. [Policy 3205: Vendor Selection](#); and
  - v. [Standards of Business Conduct](#).

**IV. Gifts**

- a. Clinical Personnel shall not accept personal gifts from industry representatives<sup>3</sup> under any circumstances.
- b. In this Policy, the term "gift" means any item, product, or service, regardless of the nature, purpose, or value, except in the limited circumstances described below. The term includes, but is not limited to, pens, pads, and other promotional items; cash; food and drink, except in the limited circumstances described in Section V of this Policy; entertainment such as tickets to events, golf, and other sports outings; hotels, transportation, and other travel expenses, except in the limited circumstances described in Section XI of this Policy; stock, equity, and other ownership interests; discounts on products or services.
- c. The following are not considered "personal gifts" under this Policy:
  - i. Books, charts, or other materials used for patient care or for training purposes may be accepted if distributed through the relevant department;
  - ii. Payments for contractual services may be accepted if the engagement complies with this policy (see the **Consulting** and **Industry-sponsored Educational Programs** sections below); and

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<sup>3</sup> In this Policy, the term "industry representatives" means all sales, marketing, or other personnel who promote industry products.

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- iii. Unrestricted educational funds provided to a School of Medicine department.

**V. Meals**

- a. Industry-supplied or supported food or drinks are considered personal gifts and may not be accepted by Clinical Personnel on-campus or off-campus, except in the limited circumstances discussed below.
- b. Industry-supplied food or drinks may only be accepted:
  - i. if provided in connection with attendance at programs compliant with the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support;
  - ii. as a reasonable and necessary travel expense associated with services rendered in accordance with Section XI of this Policy (e.g., approved consulting activity); or
  - iii. if provided in connection with attendance at scientific or professional society meeting events open to all meeting attendees.

**VI. Consulting**

- a. Clinical Personnel may consult with industry subject to the following requirements:
  - i. the engagement must be governed by a written agreement specifying the service(s) to be provided and the compensation to be paid;
  - ii. payment must be at fair market value and must be commensurate with the time and effort for the contractual services; and
  - iii. Clinical Personnel consulting for industry must disclose the engagement as required under this Policy and the Policy on Conflict of Interest and Conflict of Commitment.
- b. Consulting engagements involving compensation without commensurate time and effort are considered personal gifts and are prohibited under this Policy.

**VII. Drug Samples**

- a. Clinical Personnel may accept free drug samples from industry for distribution to patients, particularly those who lack financial access to the medications, with the following limitations:

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- i. Clinical Personnel should be cautious in distributing medications that are not on formulary since distribution of non-formulary drugs to patients may encourage use of costlier medications;
- ii. Free drug samples may never be sold; and
- iii. Free drug samples may never be used by Clinical Personnel for themselves or family members, except when prescribed and/or dispensed by a physician.

**VIII. Site Access by Industry Representatives**

- a. Industry representatives are permitted in non-patient care areas by appointment only. Appointments will be permitted only on the invitation of Clinical Personnel.
- b. Industry representatives are strictly prohibited from entering patient care areas except in the limited circumstances described below:
  - i. The purpose of the industry representative's presence must be to provide in-service training or assistance to Clinical Personnel on devices or equipment;
  - ii. Clinical Personnel must be present at all times during the patient care interaction; and
  - iii. Disclosure must be provided to the patient (or to his/her family) that industry representative(s) may be present in the procedure area.
- c. For the purpose of this Policy, in-service training and interactions with industry to evaluate devices or equipment are not considered "educational programs" and are not subject to the requirements in the sections pertaining to education (below).

**IX. Industry Support of Continuing Medical Education**

- a. All industry-sponsored continuing medical education (CME) events on the Yale campus must be compliant with the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support in effect on September 1, 2010. The following is a summary of selected ACCME Standards (last revised in 2007):
  - i. All decisions concerning educational needs, objectives, content, methods, evaluation and speaker must be free of commercial influence (ACCME Standard 1.1);
  - ii. All persons in a position to control the content of an educational activity must disclose all relevant financial relationships to the

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provider of the CME and to the audience at the beginning of the educational activity (ACCME Standards 2.1, 6.1);

- iii. All conflicts of interest must be identified and resolved prior to the educational activity being delivered (ACCME Standard 2.3);
- iv. Product-promotion material or product-specific advertisements of any type are prohibited in or during CME activities (ACCME Standard 4.2);
- v. Educational materials that are part of a CME activity, such as slides and handouts, may not contain any advertising, trade name, or a product-group message (ACCME Standard 4.3);
- vi. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity (ACCME Standard 5.1); and
- vii. The CME provider may not use commercial support to pay for travel, lodging, or other personal expenses of attendees (ACCME Standard 3.12).

(The full text of the Standards is available at <http://www.accme.org/> )

- b. In addition to the aforementioned ACCME Standards, industry-sponsored CME events on the YSM campus must also comply with the following provisions:
  - i. Gifts or compensation may not be provided solely for attendance at the meeting or lecture; and
  - ii. Industry funds to support the specific educational activity must be given directly to the University in accordance with University policy and may not be provided directly to Clinical Personnel.
- c. The YSM Center for Continuing Medical Education (Yale CME) is the exclusive provider of accredited continuing professional development for Clinical Personnel.

**X. Industry-sponsored Educational Programs (off-campus)**

- a. Clinical Personnel Participation in Off-campus Educational or Training Programs (Organizer, Author, Speaker)

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Clinical Personnel may actively participate (e.g., by giving a lecture, organizing the meeting) in industry-sponsored meetings or lectures only if all of the following requirements are met:

- i. Financial support by industry must be fully disclosed at the meeting by the sponsor;
- ii. The meeting or lecture's content, including slides and written materials, must be determined solely by the participating Clinical Personnel with no influence from the sponsor;
- iii. The lecturer must promote objective scientific and educational activities and discourse;
- iv. Clinical Personnel must not be required by the industry sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor's contribution of funds or services;
- v. If Clinical Personnel are organizing the meeting, then they must ensure that attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, or provision of food or gifts);
- vi. If Clinical Personnel are organizing the meeting, then they must ensure that gifts of any type are not distributed to attendees before, during, or after the meeting or lecture;
- vii. The engagement must be governed by a written agreement or memorandum specifying the service(s) to be provided. Compensation must be limited to reimbursement of reasonable and necessary travel expenses as described in Section XI of this Policy, and an appropriate honorarium;
- viii. The lecturer must explicitly describe all of his or her relevant financial interests (recent, existing, or planned) to the audience prior to the lecture; and
- ix. Clinical Personnel actively participating in industry-sponsored meetings or lectures must disclose the engagements and total annual compensation as required under the University Policy on Conflict of Interest and Conflict of Commitment.

b. **Clinical Personnel Attendance in Off-campus Educational or Training Programs**

Clinical Personnel may attend off-campus industry-sponsored programs only if all of the following requirements are met:

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- i. The program must be primarily educational and designed to provide evidence-based medical or scientific information or to promote evidence-based clinical care and/or to advance scientific research;
  - ii. The industry sponsor may not reimburse the travel expenses of attendees; and
  - iii. Attendees may not receive gifts or other compensation for attendance.
- c. Clinical Personnel should not attend or participate in industry-sponsored off-campus events for primarily promotional/marketing purposes.

**XI. Travel Expenses**

- a. Clinical Personnel may not accept travel funds from industry, except for legitimate reimbursement of reasonable and necessary travel expenses in the following circumstances:
  - i. to provide services rendered in accordance with the terms of a written agreement (e.g., approved consulting activity); or
  - ii. for in-service training or on-site inspection and demonstration of capital equipment or devices.

**XII. Authorship**

- a. Clinical Personnel are prohibited from being listed as an author on an article unless they make a substantive contribution to the content of the article. Industry representatives or others retained by industry that contribute to an article on which Clinical Personnel appear as authors must be listed as contributors or authors on the article and their industry affiliation must be disclosed in the published article.
- b. The practice of being named as an author on an article that contains substantial portions written by someone who is not listed as an author (i.e., ghostwriting) is unacceptable under all circumstances.

**XIII. Scholarships/Fellowships/Other Educational Funds for Trainees**

- a. Industry support for scholarships, fellowships, or other educational programs for trainees must comply with all of the following:
  - i. The funds must be given directly to the School of Medicine Department or Section in accordance with University policy and may not be provided directly to the trainee;
  - ii. The Department, Section, or Program must determine that the conference or training has educational merit;

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- iii. The industry donor may not have any input or involvement in the selection of the individual(s) that will receive the funding; and
  - iv. The recipient of the funds may not be subject to any implicit or explicit quid pro quo (i.e., “no strings are attached”).
- b. In situations where a scholarship for participation in an educational program is administered by the industry sponsor, the application must be approved in advance by the Department Chair or Section Chief.

**XIV. Disclosure of Industry Relationships**

- a. Clinical Personnel must disclose industry relationships in accordance with the University Policy on Conflict of Interest and Conflict of Commitment (view the policy at <http://provost.yale.edu/conflict-policy> ).
- b. ***Disclosure in publications:*** For articles submitted for publication in a professional journal, Clinical Personnel must adhere to the financial interest disclosure requirements of the journal. In the event that the journal does not have a disclosure requirement, Clinical Personnel must adhere to the disclosure requirements recommended by the International Committee of Medical Journal Editors in effect on September 1, 2010.
- c. ***Disclosure in presentations:*** For presentations given in connection with a meeting of a professional society, Clinical Personnel must adhere to the financial interest disclosure requirements of the society. In addition to any requirements of the society, the disclosure must comply with the ACCME Standards and the presentation must include a slide with the disclosure information.
- d. ***Disclosure to patients:*** Clinical Personnel must disclose all relevant financial interests to patients. The timing, method, and content of the disclosure shall be determined by the individual program.
- e. ***Disclosure to students/trainees:*** Clinical Personnel must disclose all relevant financial interests to students and trainees. The timing, method, and content of the disclosure shall be determined by the individual program.
- f. ***Disclosure to the public:*** The University will disclose to its patient communities information regarding the industry relationships of Clinical Personnel that relate their University responsibilities. The format and mechanism for such disclosures remain to be determined, but may include public websites, informational brochures, etc.

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**XV. Enforcement**

- a. Suspected violations of this Policy shall be referred to the relevant Department Chair and/or the Dean's Office for review. Depending on the nature of the alleged violation, the Department Chair or Dean's Office, as applicable, may coordinate with other appropriate University committees or offices in the review.
- b. Violations of this Policy will be subject to corrective or disciplinary action by the School of Medicine. The corrective or disciplinary action(s) imposed will in each case depend on several factors, including:
  - i. The seriousness of the violation;
  - ii. Whether the violation was a first or repeat offense;
  - iii. Whether the violation was inadvertent or deliberate; and
  - iv. The magnitude of the harm caused to the School of Medicine and Yale University.
- c. Potential corrective and disciplinary actions that may be imposed, singly or in any combination, for a violation of this Policy include, but are not limited to:
  - i. Further education or training for the individual on the requirements of this Policy and/or on conflict of interest principles;
  - ii. Written reprimand;
  - iii. Correction of disclosure information published by the individual;
  - iv. Restrictions on the individual's external professional relationships;
  - v. Restrictions on the individual's supervision of other faculty, staff, students, and/or trainees;
  - vi. Restrictions on the individual's research or clinical activities;
  - vii. Removal of the individual from University administrative positions; or
  - viii. Other corrective and disciplinary actions available under applicable University policies, up to and including termination.