Administrative Manual				
	UNC HEALTH CARE	Policy Name Policy Number	Vendor Relations ADMIN 0211	
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#### **Table of Contents**

Description	1
Rationale	1
A. Introduction	1
<del>y</del> ,	
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Original Policy Date and Revisions	
	A. Introduction B. Applicability C. Applicability of Other UNCHCS, UNC Hospitals, and University Policies Policy A. Reporting of Financial Relationships B. Contracting with Vendors C. Educational Activities D. Educational Materials E. External Work F. Ghostwriting and Speakers' Bureaus G. Gifts H. Meals and Other Hospitality I. Honoraria, Travel and Hospitality Associated with Consulting Activities J. Work-Related Travel K. Drug and Device Samples L. Research and Sponsored Projects M. Donations/Gifts from a Vendor N. Policy Violations

# I. Description

Provides guidelines to the Health Care System (HCS) and the University for the School of Medicine Personnel on how to engage with industry in ways that protect personal and institutional integrity.

### II. Rationale

### A. Introduction

The UNC Health Care System (HCS) and the UNC School of Medicine (SOM) share the goals of providing quality health care, first class medical education, and transformational research consistent with the highest principles of integrity. Interaction with Vendors can support the mission of the HCS and the SOM of service, education, and research, but should not compromise patient confidentiality, interfere with patient care, bias research results, or bias the education of residents, students, patients, or the public.

When conducted ethically and transparently, interactions with Vendors can result in benefits to our patients and trainees. It is appropriate and oftentimes necessary, for example, for faculty members to become involved at various stages of drug and device development so that they can assist with the development of products and services that will benefit their patients and society. Appropriate contacts with industry sales representatives also provide learning opportunities about new therapeutic options, research products and other services or supplies.

In all these activities, the safety and well-being of our patients and the integrity of our institutions must be our foremost concern. This Policy, adopted jointly by the HCS and the University for the School of Medicine, is designed to enable HCS and SOM Personnel to engage with Vendors in ways that protect personal and institutional integrity.

# **B.** Applicability

For purposes of this Policy, a "Vendor" is described as any business that provides or has potential to provide services or products to the HCS or to the SOM. This Policy applies to all HCS employees, and to all SOM employees, students and trainees, faculty, regardless of the location at which they work or are assigned (collectively, "Covered Personnel.")

Financial relationships of family members of Covered Personnel are considered to be the same as the relationships of the Covered Personnel. These relationships are also subject to disclosure and regulation as provided under this and related policies. "Family Members" includes one's spouse and dependent children. For the purposes of this Policy, "spouse" includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations.

# C. Applicability of Other UNCHCS, UNC Hospitals, and University Policies

This Policy supplements existing UNC HCS, UNC Hospitals, and UNC-Chapel Hill policies, including, but not limited to:

- UNCHCS ADMIN 0179: <u>Vendor Representatives Policy and Visitation Guidelines</u>.
- UNC Hospitals SSPC 0001: Surgical Services Product Committee
- University of North Carolina: Policy on Conflicts of Interest and Commitment and
   "Regulations on External Professional Activities for Pay by Faculty and Non-faculty EPA
   Employees".
- UNC-Chapel Hill Policy on Individual Conflicts of Interest and Conflicts of Commitment.
- UNCHCS Policy ADMIN 0112: Medication Management: Drug Samples

In the event of any discrepancy between the provisions of this Policy and provisions of the Policies and procedures set out above, the provisions of this Policy shall control.

#### III. Policy

#### A. Reporting of Financial Relationships

For purposes of this Policy, a Financial Relationship shall be the possession or receipt by Covered Personnel or a Family Member of:

- Income, in any form and in any amount and for any purpose, received from a Vendor.
- Ownership, in any form (including stock options or warrants) other than through a mutual fund in a Vendor.
- In-kind compensation from a Vendor such as the provision of goods, travel, or lodging.
- Royalties, including royalties received through the University, originating from a Vendor.
- Gifts made for the benefit of a Covered Individual by a Vendor to the University, UNCHCS, or any affiliated foundation of either entity.

A financial relationship may exist whether the Covered Individual is paid directly or whether compensation is routed through another legal entity, such as a limited liability company or non-profit organization.

The reporting requirements of this Policy are supplemental to and are required in addition to any reports required under the University's "Policy on Individual Conflicts of Interest and Commitment", "Institutional Conflicts of Interest", or "External Professional Activities for Pay" or applicable HCS Policies.

Covered Personnel are required to report a financial relationship at least annually and more often as needed to disclose new relationships through the entities' online reporting structure. This information will be reviewed and approved by the departmental chair or supervisor. Such arrangements can be subject to scrutiny under fraud and abuse regulations. Failure to disclose financial relationships as required under this Policy may result in disciplinary action up to and including dismissal. Contact the HCS Compliance Office or SOM Dean's Office, as applicable, for any questions related to financial relationships. Covered Personnel are also required to confirm annually all financial relationships, if any, previously disclosed during the year through the entities' online reporting structure.

B. The financial information reported under this Policy shall become part of the personnel record of the Covered Individual. Access to information disclosed under this Policy will be limited to those who need to know for business purposes, which includes the supervisors of Covered Personnel who must review proposed activities prior to initiation. Contracting with Vendors

Contracting with Vendors on behalf of the SOM or HCS must be accomplished through the appropriate Purchasing Department. Covered Personnel are generally prohibited from participating in the negotiations with any Vendor with whom such Covered Personnel have a personal interest, a financial interest, or personal or family relationship. Covered Personnel may, however, provide professional advice to the persons reviewing specific goods and services, provided that they disclose any potential conflict of interest to those whom they are advising.

#### C. Educational Activities

"Educational Activities" are activities, conferences, or meetings organized at or through the University or the HCS and primarily dedicated to promoting scientific and educational activities and to furthering the knowledge of the attendees on the topic being presented. Educational Activities include Continuing Medical Education ("CME") events. Covered Personnel must adhere to the ACCME Standards for Commercial Support guidelines and other University or HCS Policies when organizing, holding or presenting and Educational Activity. Vendors may sponsor Educational Activities by making an unrestricted donation or educational grant to the SOM or HCS, but in no case may a vendor dictate or control the selection of speakers, topic, or educational material presented. Vendor representatives may not speak at Educational Activities or provide refreshments or personal gifts to attendees.

#### D. Educational Materials

Vendors are not permitted to distribute post or leave any type of printed or handwritten material, advertisements, signs, or other such promotional materials anywhere at the SOM or HCS, unless specifically requested by faculty or staff. Vendors may leave educational materials regarding their goods or services that may be useful to patients with the applicable department administration, but Vendors may not distribute them directly to patients. All such educational

information should be reviewed by and distributed by the appropriate department. Educational materials, such as textbooks or medical journals which benefit patients, may be provided by a Vendor to the SOM or HCS, if such materials serve a genuine educational function. No promotional material or product information from the Vendor may be attached to any such item.

# E. External Work

Disclosure by Covered Personnel of proposed external professional activities for pay is required in advance of undertaking such activities. Such is the case whether Covered Personnel are compensated directly by the outside entity or they direct that the compensation be paid directly to the University, SOM, HCS, or an affiliated foundation. Disclosure is also required whether the Covered Personnel are paid directly or paid through another legal entity, such as a limited liability company or a non-profit organization. External professional activities for pay do *not* include services rendered pursuant to a contract between the University and the external entity for which the services are undertaken.

Covered Personnel who have received permission from their supervisors may consult for Vendors for compensation and use or prescribe those Vendors' products in patient care or research *only if*:

- 1. They comply with the University or HCS Policy on External Professional Activities for Pay;
- 2. Their department chair or supervisor has approved, through the appropriate reporting mechanism, and they have disclose the amount of compensation they expect to receive from the proposed consulting activity at least ten days prior to the activity;
- 3. Their supervisor determines that any consulting relationships, including projected compensation, are not excessive; and
- 4. The supervisor determines that such activities will not interfere with the employment obligations of the affected Covered Personnel.

It is understood that there may be changes in approved consulting arrangements during a given academic/fiscal year. Covered Personnel are responsible for submitting an amended disclosure form that addresses any such changes, including changes in the amount of time or compensation involved. This amended disclosure form must be submitted not later than thirty (30) days after Covered Personnel learn of the changes in the terms of the approved consulting arrangement.

Failure to disclose and obtain approval for consulting activities prior to the engagement as required by policy may result in disciplinary action up to and including dismissal.

## F. Ghostwriting and Speakers' Bureaus

Participation in speakers' bureaus and publication and delivery of ghostwritten works for compensation are considered types of external professional activities for pay.

For purposes of this Policy, "ghostwriting" is the practice of allowing someone other than the named author to write a paper or presentation delivered or reported to be written by the named author. Covered Personnel are not allowed to engage in ghostwriting under any circumstances.

For purposes of this Policy, "speakers' bureaus" are defined as panels of experts who deliver talks or papers for compensation in any form for the promotion of a product, service, or device

manufactured or marketed by the entity directly or indirectly providing such compensation. Covered Personnel are not allowed to participate in speakers bureaus under this Policy. The conditions of the speaking engagement will govern the decision as to whether the activity is acceptable under this Policy.

Covered Personnel may participate in speaking engagements that are sponsored by a Vendor(s) where:

- 1. the Covered Personnel retains full editorial control and authority over the content of the presentation; and
- the content of the lecture is educational, free from commercial influence, and is not designed to recommend specific drugs, devices, or other commercial products or services; and; and
- 3. the content of the lecture is based on best available evidence and reflects a balanced assessment of the current science and treatment options; and
- 4. the event sponsor does not provide honoraria or gifts to the attendees; and
- 5. any required attestations are made at the beginning of the presentation that disclose all funding and editorial relationships with the Vendors, including an attestation of receipt of honorarium for providing the talk to the program attendees; and
- 6. the slides do not contain any logos or names of the company that sponsored their production, except as required in the attestation; and
- 7. in the estimation of the supervisor authorized to approve the consulting activity, any honorarium and travel expenses paid for the speaker's participation are reasonable.

While prior review of the presentation by a Vendor is acceptable, Covered Personnel should NOT allow a Vendor through such review to influence the content of the presentation. If the supervisor has concerns about possible overreaching by a Vendor in conjunction with a specific presentation, the supervisor may require that he or she review and approve the slides prior to the presentation.

### G. Gifts

Covered Personnel may not receive gifts of any nature and of any value from Vendors. Even items of a relatively trivial value that incorporate a product or company logo (such as pens, notepads, or desk items) may provide an inappropriate opportunity for the company to market to Covered Personnel, to patients, and to other members of the public. This prohibition includes any tangible enticement, whether in cash, extra goods, services, or gifts, which are offered by a Vendor to encourage the use or purchase of the Vendor's product. Covered Personnel may not accept payment, gifts, or other benefits in return for completing evaluations or surveys developed by a Vendor.

This prohibition includes gifts to the family of Covered Personnel and to legal entities, such as limited liability companies, through which Covered Personnel might engage in consulting activities.

# H. Meals and Other Hospitality

Covered Personnel may not accept meals or other hospitality from Vendors, except in the following circumstances:

1) Meals that are served as part of a general professional conference or meeting supported in whole or in part by Vendor(s) and included in the event registration. (e.g., annual meetings of academic societies where lunch is served to all registered attendees), and

2) Meals provided in conjunction with off-site activities as part of approved consulting activities (as provided in the section "Honoraria, Travel and Hospitality Associated with Consulting Activities" below)

Covered Personnel must pay for their own meals if attending an educational meeting or journal club organized by a Vendor as an invitation-only event and held at a restaurant or resort.

Under no circumstances may Covered Personnel accept complimentary tickets to sporting or other events from a Vendor.

3) UNCHCS sometimes permits vendors of interest to our employees to set up information tables in the lobby of the UNC Hospitals. With advance approval by the sponsoring office (generally Employee Recreation & Wellness or Volunteer Services) and Compliance for those vendors, it will not be a violation of this policy for employees to receive small gifts (limited to items that have a relatively trivial or de minimis value) from or participate in a "drawing" for prizes offered by these vendors. By way of example, a local bank may set up an information table to provide employees information about banking services and offer a pen or other small token with the bank's logo and information. The office sponsoring the event is responsible for seeking approval of any such gifts in advance from Compliance and responsible for ensuring that the vendor abide by all policies and restrictions placed that vendor's activities on the premises. Vendors may not offer food or health assessments of any kind.

# I. Honoraria, Travel and Hospitality Associated with Consulting Activities

Compensation, travel reimbursement, and hospitality associated with external professional activities for pay must be reasonable and consistent with the educational or scientific purpose of the event. Covered Personnel may not accept company reimbursement for travel, meals, or lodging for family members in conjunction with Covered Personnel attendance at meetings, conferences, etc.

## J. Work-Related Travel

Covered Personnel may not directly accept reimbursement or sponsorship for travel and expenses for site visits for training or to evaluate a product or service. Vendor-sponsored visits by Covered Personnel to Vendor sites for training are acceptable if the cost of such training visits is itemized in the quotation and included in the signed final contract. Reimbursement should be requested through the appropriate University or HCS office. University and HCS Covered Personnel may take site visits to evaluate a product or service at the Vendor's expense, provided that:

- All arrangements related to site visits, including selection of participants, duration of the visit, selection of travel method and accommodations, are made by the applicable department.
- 2. Site visits at the expense of the Vendor may only include travel, housing, and food expenses specifically related to the evaluation of the product or service and incurred in accordance with departmental policies regarding the appropriateness of business expenses and within spending guidelines for expenses, including per diem payments, business class travel, and hotel accommodations. Expenses may not include any extra expenses which are personal in nature or unrelated to the evaluation.
- 3. All expenses will be determined and paid for by the applicable department with the reimbursement made to the Covered Personnel through the usual process. The

Department will send an invoice for appropriate expenses to the Vendor for reimbursement.

# K. Drug and Device Samples

Drug or device or other product samples given to Covered Personnel by Vendor representatives must be deposited and distributed according to the HCS Policy ADMIN 0112, Medication Management: Drug Samples, where that Policy is applicable. Where such samples are provided for research or other non-clinical purposes, acknowledgement of the donation must be made by the University or HCS through appropriate channels. No service, right, or license may be given to the donor in conjunction with the gift of the sample except through a written contract signed by an authorized official.

# L. Research and Sponsored Projects

All research activities, including but not limited to the use of investigational drugs must be conducted pursuant to University or HCS policies and procedures concerning research. It is the obligation of the Covered Personnel to learn about the applicable policies and procedures before beginning any research projects. Promotional activities by Vendors may not be performed under the guise of research. HCS Covered Personnel who participate in research are covered by the University's Policy on Conflict of Interest and Commitment for their research duties and activities. (see Section II B: Applicability of Other UNCHCS, UNC Hospitals, and University Policies for the complete Policy).

### M. Donations/Gifts from a Vendor

Vendors may provide unrestricted donations to a department. Those donations can be mailed to the Finance & Business Operations Office, attention Vendor Relations Account 145 Medical Drive, CB 9515, Chapel Hill, NC 27599-9515. Reference the department name when making donations.

## N. Policy Violations

Covered Personnel who are aware of potential violations of this policy should report those allegations to the University or HCS Compliance Office, University Counsel, or to University or HCS Compliance Hotline. Alleged violations of this policy shall be investigated by the HCS or University Compliance offices. On finding of a violation of this policy, the supervisor of the Covered Personnel involved will be notified in writing of the facts and nature of the policy violation. The applicable Compliance Office will work with Human Resources to recommend disciplinary action or other action provided under this policy. All disciplinary action taken hereunder shall follow the established procedures of the University and HCS. In addition to any sanctions specifically provided herein, Covered Personnel found to have violated this policy will be subject to disciplinary action up to and including dismissal.

### IV. Original Policy Date and Revisions

Dec 2010

**Revision October 2013** 

Revision June 2014