

**UNC HEALTH CARE SYSTEM
UNC SCHOOL OF MEDICINE**

**POLICY ON VENDOR RELATIONSHIPS RELATED TO
BIOMEDICAL RESEARCH OR PATIENT CARE**

FREQUENTLY ASKED QUESTIONS

I. Policy Objectives and Purpose

- (1) Why do we need a policy regulating relationships with Vendors in regard to patient care and biomedical research activities?

UNC School of Medicine and UNC HealthCare strive to be a first-class academic medical center. Implicit in that goal is providing quality care to our patients and conducting research without the appearance of improper influence. This policy is necessary to demonstrate internally and externally that the School of Medicine and the HealthCare System have defined appropriate interactions with external entities and have identified those outside interests that could affect or could be perceived to affect the integrity of clinical decision-making.

- (2) What is the purpose of this policy?

This policy is designed to give guidance to clinician, other healthcare system professionals and researchers navigating the complex landscape of clinical, educational and administrative duties, private sector relationships, professional guidelines, and public perception. The intention is to raise awareness of the various ways conflicts of interest may arise and to provide mechanisms to ensure appropriateness and transparency. It is not intended to challenge individual ethics or to punish individuals who find themselves in conflicted situations they could not reasonably anticipate.

- (3) Does this policy apply to me if I do not perform research or come into contact with patients?

Yes. The policy applies to UNC Hospitals employees, UNC Health Care System employees paid through the UNC Campus and Health Care System payroll, and UNC faculty, staff and students regardless of their job classification.

- (4) Does this Policy apply to other UNC HCS hospitals, i.e., Rex, Chatham, or Triangle Physician Network?

Initially, the Policy is only being rolled out to the UNC Campus.

II. Public Disclosure

- (1) Why do my relationships with pharmaceutical and medical device companies and Vendors of research equipment and supplies have to be disclosed publicly?

To provide transparency to our patients and other stakeholders who may feel that these relationships are relevant to healthcare decision-making. An additional reason to disclose this information is that in the near future, most major pharmaceutical and medical device companies will be making annual public disclosure of the names of physicians who have received honoraria, research support and other payments over the preceding year. Having our own reporting requirement will allow the University and Health Care System to readily identify and request correction of errors or discrepancies in the information disclosed by other entities regarding UNC personnel.

- (2) Will the amount of my financial relationships be publicly disclosed?

Yes. The Policy will be consistent with the emerging practice among pharmaceutical and medical device companies to make full disclosure of amounts paid to or on behalf of physicians.

- (3) My spouse works for a pharmaceutical company. Do I have to disclose his/her income and stock options under the Policy?

Yes, the Policy requires that you disclose these Financial Interests to the University. However, his/her Financial Interests associated with their employment will not be publicly disclosed by the University.

III. Meals and Other Hospitality

- (1) Can a Vendor representative bring in lunch for me and/or my staff?

*No. The policy specifically prohibits gifts, food or entertainment provided by a Vendor representative except that one may accept food or a meal as part of a general professional conference or meeting. (For purposes of the Policy, a **“Vendor” is a business that manufactures or provides products or services used in patient care or in research.**) A workplace presentation by a Vendor representative would not be considered a “general professional conference or meeting” under the policy.*

- (2) The Policy allows Covered Personnel to accept a meal that is part of a “general professional conference or meeting.” What is a “general professional conference or meeting”?

It is perhaps easier to define a “general professional conference or meeting” by stating what is NOT. Generally a gathering would NOT be considered a “general professional conference or meeting if it were:

- *Sponsored or underwritten by a Vendor; and*
- *Organized for the purpose of promoting use of a Vendor’s products or services;*

December 16, 2010

Where a meeting is held on an invitation-only basis and is not open to general registration, it is likely NOT a “general professional conference or meeting.” Invitation-only gatherings held at restaurants rather than at a conference facility (such as a hotel, convention center, or a facility such as the William and Ida Friday Center) are particularly suspect.(See F.A.Q. #6 below.)

Meetings or conferences sponsored by a professional association, institution of higher learning or other entity whose purpose is to promote healthcare and/or education rather than to manufacture, consult, sell, or distribute products or services that might be used by healthcare providers or patients will generally be considered “general professional conferences or meetings” for purposes of determining whether Covered Personnel may accept a meal or other food and drink without paying for it while attending the gathering.

(3) Can we provide food through University or hospital catering and have expenses reimbursed by a company?

No. Again the policy prohibits gifts, food or entertainment to be provided by a Vendor representative. For purposes of this policy, there is no distinction between providing reimbursement for food and providing the actual food.

(4) Is the answer different if no credit is given to the sponsoring company?

No. However the institution is free to accept unrestricted gifts from Vendors that must be deposited into a special account with the Medical Foundation. The unrestricted funds can be directed to food expenses on an application basis by the chair or director.

(5) May I accept an invitation from a company inviting a group to an off-site meal held at a restaurant or similar facility?

You may attend, but must pay your own expenses.

(6) Why does the Policy allow me to accept a meal at a general professional conference or meeting supported in whole or in part by a drug or device manufacturer but not to attend an invitation-only dinner sponsored by such a company, which may include an educational component?

Conferences or meetings with open registration, whether or not approved for CME credit, pose less of a risk of undue influence than do invitation-only dinners held at restaurants, banquet facilities, etc. The Policy recognizes that it would be a hardship for covered personnel to leave a day-long meeting, possibly held at a relatively isolated conference facility, to eat elsewhere. Moreover, conference or meeting luncheons often include speakers or presentations that are part of the educational value of the conference.

(7) I discovered that a company paid for my dinner when it was too late for me to pay separately. I appear to have violated the policy. What do I do?

December 16, 2010

Employees should make their best efforts to cover their own meal expenses, including alerting the host company in advance that this is the policy of your employer, asking the restaurant for a separate check and attempting to reimburse the company. If all efforts fail, review the circumstances with your supervisor to determine appropriate action. No further reporting is required.

(8) Does this apply to nurses and other healthcare professionals?

Yes. The policy applies to all employees of UNC Hospitals and UNC Medical School.

(9) I am a trainee on rotation and corporate hospitality is being provided at my practice site. What should I do?

Trainees are expected to adhere to UNC Health Care System and Medical School policies and this guidance document. These requirements are not intended to interfere with the benefits of the rotation experience. Where adherence is not possible, report the circumstances to your supervisor or training director as soon as possible.

(10) May a company take me to lunch in conjunction with my personal consulting activities?

Yes. Reasonable meals are acceptable as part of an approved external professional activity for pay, separate from your University duties.

(11) Our department has a contract with a Vendor and it states that we will allow the Vendor to bring in potential clients to review the product and meet with staff members to discuss the product. Can the Vendor provide lunch to our staff?

Yes. The Policy states that “covered personnel engaged off-site in approved consulting activities may accept meals provided in conjunction with such activities.” Since this activity is essentially a consulting agreement the employees can accept the meal as long as it is reasonable.

(12) We have Vendor representatives from a UNC-approved disability insurance company requesting a lunch-and-learn session with residents. Can they provide lunch to the residents?

Yes. This Policy only relates to manufacturers/Vendors that provide products and services used in patient care and research, so the disability insurance company would not be a Vendor for this policy.

(13) Can departments still solicit money from Vendors to support departmental events or activities?

Yes, but the department should not convey an advantage to any Vendors, should not allow significant restrictions for use of the funds, and should not pass the benefits through the specific individuals.

IV. Gifts and Promotional Materials

(1) The Policy requires disclosure of “Gifts made for the benefit of an individual Covered Personnel by a Vendor to the University, UNCHSC, or any affiliated foundation of either entity”. I thought that gifts were prohibited by the Policy?

The Policy prohibits some gifts yet requires disclosure for certain types of gifts. This provision requires that you report PERMITTED GIFTS. Personal gifts, for the benefit of a specific individual (i.e. pens, notepads, thermos, desk supplies, sporting event tickets) are prohibited by the Policy. However, gifts made to the School of Medicine, Health Care System, or affiliated foundation for the benefit of the professional activities of a specific faculty/staff member/student/trainee are ALLOWED. The person receiving that particular type of gift must report it. Although it is not the legal property of that individual, it is a financial interest in that Vendor that must be disclosed.

(2) What are some examples of gifts that are allowed but must be disclosed under the Policy?

The following are examples:

- a. Vendor A donates money to the University or an affiliated foundation to support Dr. X’s research on cardiovascular disease.*
- b. Vendor A donates a microscope to Dr. X for use in his/her University research.*
- c. Vendor A gives Dr. X a cutting-edge piece of technology for Dr. X to advance his/her studies in xyz.*

After receiving any of these gifts, Dr. X must report the gift to UNCHCS and/or SOM as a financial interest in Vendor A.

(3) The policy prohibits gifts of any value. What about branded items I receive in the mail or at conferences?

When it is practical to decline promotional items, one should do so. However, receiving promotional items of nominal value (e.g. pens, notepads) provided through mass marketing mailing efforts or included in conference registration materials is not a policy violation. Such items should not be brought into the practice site, office, laboratory or other UNC/UNCHCS facilities, and if they are received in these locations should be removed and not made visible to patients or other members of the public. Similarly, family members may receive such promotional items without violating policy. These items should not come to the practice site, office, laboratory, or other UNC/UNCHCS facilities.

(4) May my spouse accept gifts when attending a professional conference with me?

No.

December 16, 2010

(5) My spouse is a health care professional not employed by UNC. May they accept gifts in their own right when attending a professional conference with me?

Yes. The Policy can only regulate the activities of covered personnel. Your spouse cannot accept gifts occasioned by your actual or prospective relationship with a company, but is free to follow their own principles or employer policies in terms of their own conduct vis-à-vis Vendors.

(6) Why is UNC concerned about items of trivial value such as pens and notepads?

We join our peer institutions in recognizing that even items of trivial value can create an inference of bias. We concur with others that gifts, even small gifts, carry an implied expectation of reciprocity.

(7) A company sent a fruit basket to my office. May I remove identifying information and make it available to support staff or trainees?

Yes. This constitutes a gift to the institution and is appropriately shared with institutional personnel once de-identified.

(8) Does the policy allow for patient education brochures, demonstration devices and supplies provided by companies for patient use?

Yes. These items may be accepted for distribution to patients provided 1) they are not given directly to patients by Vendors, and 2) the attending physician determines that the educational and/or patient welfare benefit outweighs the promotional value.

(9) Does the policy prohibit gifts of textbooks?

Yes. However, the institution may accept a gift of textbooks and distribute them provided the company is not identified on either the book or its packaging.

(10) As a part of an educational skull base surgery course, a Vendor wishes to donate a drill, a head holder, skull pins and other material for non-clinical use. Is this allowed under the new Policy?

Yes. This gift would be to the University so it is allowed and would not create a responsibility for anyone to report this on his/her annual disclosure form.

(11) Can we accept discount vouchers from pharmaceutical Vendors to give patients?
Yes

(12) I am participating in a charity fundraiser. Is it permissible to inform vendors about the charity and solicit voluntary donations?

Yes, but you must solicit from all competing Vendors and keep an accounting of the funds in a special account at the Medical Foundation of North Carolina.

V. Ghostwriting and Speakers Bureaus:

(1) What is “ghostwriting”?

*As set forth in the policy, ghostwriting is the practice of allowing someone other than the named author to write a paper or presentation delivered or purported to be written by the named author. **Covered personnel are not allowed to engage in ghostwriting under any circumstances.***

(2) I sometimes incorporate slides provided by industry into my presentations to present information on a product or on clinical studies conducted elsewhere. Is this a violation?

Yes, Section 4.3 in the ACCME Standards states that educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or product-group message. Further guidance from the Accreditation Council for CME stated that materials furnished by commercial interest cannot be used in the CME activity. Please note, regardless if your event is CME accredited or not, you must abide by these rules.

(3) Similarly, I may appear as an author on manuscripts describing studies conducted by multi-site teams in which I participate.

This is an appropriate scholarly activity that does not constitute ghostwriting provided rules of authorship are applied without regard to the authors’ institutional affiliations.

(4) If manuscripts are drafted by industry partners, does that violate the ban on “ghostwriting”?

Possibly. Articles authored collaboratively by research teams, where all have the opportunity to review and edit the content, do not constitute “ghostwriting”. The term applies specifically to situations where the content is developed by a non-credited author and credited to someone else.

(5) A company has approached me about serving on their “speakers’ bureau” to give non-branded educational talks using slides provided by the company. May I do so?

Yes. The policy prohibits delivering talks that support a drug or device manufactured or marketed by the sponsoring company. Talks that do not speak to specific commercial products may be given provided they conform to the requirements in Section D of the Policy.

VI. External Professional Activities

(1) I’ve already disclosed my consulting relationship as required by the Policy on External Professional Activities for Pay. Is that all I have to do? Is approval for External Professional Activities for Pay (IV.B.) and Public Disclosure of Financial Relationships (IV.C.) the same thing?

No. Approval of an External Professional Activity for Pay (IV.B.) and Public Disclosure of Financial Relationships under this Policy are two separate though often related mechanisms. UNC System policy requires every EPA employee to have an approved <https://cfx.research.unc.edu/epap> on file before beginning a compensated consulting, speaking, or other non-University activity related to his/ her professional expertise. These forms are reviewed and approved/disapproved by the immediate supervisor and reported annually to General Administration. A consulting relationship reportable under the Policy on External Professional Activities for Pay may constitute a “Financial Relationship” appropriate for public disclosure under this Policy. Other types of reportable Financial Relationships, not disclosed through the Policy on External Professional Activities for Pay, include ownership of stock, royalties, gifts and income to family members.

In addition, faculty engaged in research and/or administrative leadership positions may report some of this information through the on-line Conflict of Interest disclosure process. Conflict of Interest disclosures are confidential personnel materials and are not posted publicly.

(2) What is the supervisor’s responsibility for approval of External Professional Activities?

Supervisors are responsible for determining whether outside activities can be undertaken without interfering with the employee’s UNC responsibilities. Such interference is considered a Conflict of Commitment. In assessing Conflict of Commitment the supervisor should take into account the amount of time each external activity will require, coverage needed for institutional duties missed, and the involvement of any University or HealthCare System resources in the proposed activity. A Conflict of Interest analysis is also necessary and generally considers the reasonableness of compensation and whether in light of one’s UNC responsibilities the outside interest may create the perception of or an actual conflict of interest.

(3) I am a supervisor asked to review an External Professional Activity for Pay for a subordinate to consult with a company in which I have a personal interest. What should I do?

You should disclose your conflict to your next higher supervisor and request a review, recusing yourself from the process.

(4) Is there a difference between part-time and full-time employee policies for engagement in External Professional Activities for Pay?

No.

(5) Why is the School/HealthCare System restricting my activities when I am off duty?

The policy seeks to limit employees' activities outside of their work hours only when those activities could compromise or appear to compromise their professional decision-making or the trust of our patients.