

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

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

I. Introduction

The UNC Health Care System (“UNCHCS”) and the UNC School of Medicine share the goals of providing quality health care consistent with the highest principles of integrity and providing first class medical education. In addition, the School of Medicine endeavors to engage in transformational research aimed at improving the health and well-being of society.

In seeking to accomplish these related and overlapping goals, personnel of the Health Care System and the School of Medicine can and should engage in several ways with businesses that manufacture and provide products and services used in patient care and in research (“Vendors”). Many faculty of the School of Medicine regularly undertake compensated consulting activities on behalf of Vendors. In addition, Health Care System and School of Medicine employees routinely interact with sales representatives of Vendors.

When conducted ethically and transparently, these interactions can result in benefits to our patients and trainees. It is appropriate and oftentimes necessary for faculty members to become involved at various stages of drug and device development so that, based on their highly specialized expertise in disease processes, they may positively influence the development of products and services that will benefit their patients and society. Their involvement in product development can effect improvements in patient care and outcomes that would otherwise not be possible. Moreover, appropriate contacts with industry sales representatives provide opportunities for our personnel to learn about new therapeutic options, research products, and other services or supplies, and how to use them most advantageously in their work.

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 Health Care System and the University for the School of Medicine, is designed to enable Health Care System and School of Medicine personnel to engage with industry in ways that protect personal and institutional integrity.

II. Applicability.

This Policy applies to all UNCHCS employees, to all employed faculty, and to all staff and students of the School of Medicine 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 relationships of the Covered Personnel subject to disclosure and regulation as provided under this and related policies. “Family” 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.

III. Applicability of Other UNCHCS, UNC Hospitals and University Policies.

This Policy is supplemental to the following Policies of UNCHCS, UNC Hospitals, and UNC-Chapel Hill:

- UNCHCS Policy Admin 0037: Conflicts of Interest: Interactions with Pharmaceutical and Other Vendors.
- UNCHCS Policy Admin 0178: Vendor Relations.
- UNCHCS Policy Admin 0179: Vendor Representatives Policy and Visitation Guidelines.
- UNC Hospitals Surgical Services Products Committee Procedural Guidelines.
- University of North Carolina Policy on Conflicts of Interest and Commitment Affecting Faculty and Non-Faculty EPA Employees (incorporating Policy on External Professional Activities for Pay).
- UNC-Chapel Hill Policy on Individual Conflicts of Interest and Conflicts of Commitment.

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 supersede.

IV. Policy Provisions

A. Reporting of Financial Relationships

Not less frequently than annually, Covered Personnel shall report to the University or UNCHCS, as applicable, any Financial Relationships they have with a Vendor while engaging in duties on behalf of the University or UNCHCS that involve the use, administration or prescription of that Vendor’s products or services.

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 directly or indirectly 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 gifts or the provision of travel or lodging (not including reimbursement of actual costs incurred in travel for purposes allowed under University and UNCHCS policies).
- Royalties, including royalties received through the University, originating from a Vendor.
- Gifts made for the benefit of an individual Covered Personnel by a Vendor to the University, UNCHCS, or any affiliated foundation of either entity.

The reporting requirements of this Policy are supplemental to and are required in addition to any reports required under the University or UNCHCS Policies on Individual Conflicts of Interest and Commitment, Institutional Conflicts of Interest, or External Professional Activities for Pay. Reports shall be made in a form and under procedures to be developed by the University and UNCHCS. Report forms shall be designed to allow reporting Covered Personnel to distinguish Financial Interests originating from a Family Member's employment, such as salary or stock, from other Financial Interests of the Covered Personnel and/or Family Member(s). Failure to disclose Financial Relationships as required under this Policy may result in disciplinary action up to and including dismissal.

B. External Professional Activities for Pay

Covered Personnel who are allowed to consult may do so for compensation for Vendors and use or prescribe those Vendors' products in patient care or research, *as long as*:

- (1) they comply with the University Policy on External Professional Activities for Pay or similar UNCHCS or UNC Hospitals policies; and
- (2) they disclose to their supervisor, through the appropriate reporting mechanism, the amount of compensation they expect to receive from the proposed consulting activity; and
- (3) their consulting relationships, including projected compensation, are made publicly available as provided in Section IV.C. below; and
- (4) their compensation for such activities is not deemed excessive by their supervisor¹; and

¹ For purposes of this Policy, compensation for external professional activities will not be considered excessive if, taking into account the time to be allocated to the consulting activity, the compensation does not exceed appropriate market-based compensation rates.

- (5) the relevant supervisor determines that such activities will not interfere with the employment obligations of the affected Covered Personnel.

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 in the form of a gift to the University or the Health Care System, or to an affiliated foundation.²

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 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 as required by policy may result in disciplinary action up to and including dismissal. In addition, and without foreclosing other possible disciplinary action, such Covered Personnel may be barred from participating in any external professional activities for pay for a period of time as deemed appropriate by his or her chair or supervisor.

C. Public Disclosure of Financial Relationships.

Upon adoption of this Policy, the School of Medicine and UNCHCS will confer to create the most practicable means of making Covered Personnel Financial Relationships publicly available, including consideration of an annual disclosure mechanism in addition to the disclosures required under the Policy for External Professional Activities for Pay and related UNCHCS policies.³ The mechanism adopted shall disclose Financial Relationships of all Covered Personnel, including projected compensation for consulting relationships. Covered Personnel will be required to explain and/or resolve any discrepancy between relationships they report to the University (or to UNCHCS) and any Vendor disclosures of payments or Financial Relationships.

UNCHCS treatment consent forms will be amended to include a statement notifying the patient that the patient's treating professional(s) may have Financial Relationships with Vendor(s). In addition, the treatment consent form will provide patients with information on how to discover the Financial Relationships of their treating professional(s), and will provide patients the option to request a printed copy of the information at no charge.

² Covered Personnel should consult their private tax advisors to determine whether donated consulting income is considered taxable personal income to the Covered Personnel and to what degree the gift can be characterized as a charitable contribution.

³ Such disclosure shall not include salary or other Financial Relationships created solely through the employment of Covered Personnel Family Member(s).

D. Ghostwriting and Speakers' Bureaus.

Participation in speakers' bureaus and publication and delivery of ghostwritten works for compensation are forms 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 purported to be written by the named author. Covered Personnel are not allowed to engage in ghostwriting under any circumstances.

"Speakers' bureaus" are defined for purposes of this Policy as panels of experts who deliver talks or papers for compensation in any form. **Covered Personnel are not allowed to participate in speakers' bureaus whose principal aim is the support of a product, service or device manufactured or marketed by the entity directly or indirectly providing such compensation.** However, permissible consulting may include participating as a speaker at an event where:

- (a) the content of the lecture does not recommend specific drugs, devices or other commercial products or services; and
- (b) the content of the lecture is based on best available evidence; and
- (c) the event sponsor does not provide honoraria or gifts to the attendees; and
- (d) 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 manuscripts and presentations by Vendor representatives is acceptable, Covered Personnel should be careful not to allow Vendor representatives through such review to influence inappropriately the content of the manuscript or presentation.

E. Gifts

1. Personal Gifts

Covered Personnel may not receive personal 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—provide an inappropriate opportunity for the company to market to Covered Personnel, to patients and to other members of the public.

This prohibition includes gifts to the family of Covered Personnel⁴ and to legal entities, such as limited liability companies, through which Covered Personnel engage in consulting activities. Covered Personnel may not accept company reimbursement for travel or lodging for family members in conjunction with Covered Personnel attendance at meetings, conferences, etc.

2. Meals and Other Hospitality

Generally, Covered Personnel may not accept meals or other hospitality from Vendors. However, two exceptions are allowed.

First, where meals are served as part of general professional conferences or meetings supported in whole or in part by Vendor(s), it is acceptable for registered attendees to participate in meals included in the event registration. On the other hand, Covered Personnel must pay for their own meals if attending an educational meeting organized by a Vendor as an invitation-only event and held at a restaurant or resort.

Second, Covered Personnel engaged off-site in approved consulting activities may accept meals provided in conjunction with such activities, as provided in Section IV.C.4. Such meals are considered part of reasonable compensation for consulting activities.

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

3. Gifts to the Institution

Industries and their affiliated foundations occasionally make charitable contributions to or for the benefit of the University or the Health Care System. Such gifts are appropriate and provide vital support for the University's and Health Care System's missions. As provided in the University Policy on Conflicts of Interest and Commitment, gifts and donations that have been made to the University or to a University-affiliated foundation for the benefit of the professional activities of a specific faculty or staff member or student or trainee are considered to be a *personal financial interest* of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary. Such gifts and donations, where they coincide with University activities undertaken by the beneficiary that relate to the entity making the gift or donation, may create a conflict of interest, and they must be reported by that individual as required under the Policy as well as the applicable Policy on Conflicts of Interest and Commitment.

4. Honoraria, Travel and Hospitality Associated with Consulting Activities.

⁴ This Policy does not regulate the employment activities of Family Members of Covered Personnel and hence does not prohibit the receipt of gifts by such Family Members by virtue of their own Financial Relationships, including employment relationships.

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.

F. Drug and Device Samples

Drug or device or other product samples given to Covered Personnel by industry representatives must be deposited and distributed according to the UNCHCS Policy ADMIN 0112, *Medication Management: Drug Samples*, where that Policy is applicable. Where such samples are given for research or other non-clinical purposes, acknowledgement of the donation must be made by the University or UNCHCS 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.

G. Continuing Medical Education

All educational events sponsored by the School of Medicine or UNCHCS shall comply with ACCME Standards for Commercial Support.

V. Policy Violations.

Alleged violations of this policy shall be investigated by the UNCHCS or University office authorized to enforce the UNCHCS's and University's respective conflict of interest policies. 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 and will determine whether to impose or recommend disciplinary action or other action provided for under this policy. 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.

VI. Effective Date.

This Policy is effective January 1, 2011.