

Administrative Manual

	Policy Name	Vendor Relations
	Policy Number	ADMIN 0211
	Date this Version Effective	July 2017
	Responsible for Content	Compliance

Description: This Policy provides guidelines to the UNC Health Care System (UNCHCS) and the University of the School of Medicine (SOM) Covered Personnel on how to engage with Vendors in ways that protect personal and institutional integrity.

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I. Rationale

A. Introduction

UNCHCS and the SOM share goals of providing quality health care, first class medical education, and transformational research consistent with the highest principles of integrity. Interaction with Vendors (defined below) can support the mission of the UNCHCS 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 UNCHCS and the SOM, is designed to enable UNCHCS and SOM personnel to engage with Vendors in ways that protect personal and institutional integrity.

B. Definitions

Covered Personnel: all UNCHCS and SOM employees, students, trainees and faculty, regardless of work location to which they are assigned (collectively, "Covered Personnel")

Educational Activities: activities, conferences, or meetings organized at or through the SOM or the UNCHCS, including continuing medical education ("CME") events that are primarily dedicated to promoting scientific and Educational Activities and to furthering the knowledge of the attendees on the topic being presented.

External Professional Activities: activities that are not included within the Covered Personnel employment responsibilities, if performed for any entity, public or private, other than the Covered Personnel's employer that are undertaken for compensation, monetary or in-kind, and are based upon the professional knowledge, experience and abilities of the employee.

Family Member: includes Covered Personnel'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 financial obligations.

Financial Relationship: may exist whether the Covered Personnel is paid directly or whether compensation is routed through another legal entity, such as a limited liability company or non-profit organization. Financial relationships for Family Members of Covered Personnel are considered to be the same as the relationships of the Covered Personnel and are subject to disclosure and regulations as provided under this and related policies.

Ghostwriting: 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.

Speakers' Bureau: 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.

UNC General Administration (or UNC-GA): the administrative organization of the 17 campus University of North Carolina system

University: the University of North Carolina at Chapel Hill

Vendor: any business that provides or has potential to provide services or products to the UNCHCS or to the SOM.

C. Applicability of other UNCHCS, UNC Hospitals, UNC-GA and University Policies

This Policy supplements existing UNCHCS, UNC Hospitals, UNC-GA and University policies, including, but not limited to:

- UNCHCS ADMIN 0179: [Vendor Representatives Policy and Visitation Guidelines](#).
- UNC Hospitals SSPC 0001: [Surgical Services Product Committee](#)

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- University EPAP Policy: [External Professional Activities: Faculty and EPA Non-Faculty](#)
- UNC-GA: [Policy on Conflicts of Interest and Commitment and “Regulations on External Professional Activities for Pay by Faculty and Non-faculty EPA Employees”](#).
- University [Policy on Individual Conflicts of Interest and Conflicts of Commitment](#).
- University Research Code of Conduct Policy <http://policies.unc.edu/policies/research-code-conduct/>
- University Institutional Conflict of Interest Policy <http://policies.unc.edu/files/2013/04/Institutional-COI-Policy.pdf>
- University Finance Policy 1211: [Avoiding Vendor Conflicts of Interest](#)
- 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 requirements of the more rigorous policy shall apply.

II. 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.
- Revenue from patent, copyright or other intellectual property interests, including royalties received through the University, originating from a Vendor.
- Gifts made for the direct benefit of Covered Personnel by a Vendor to the SOM, the University for the SOM, UNCHCS, or any affiliated foundation of either entity.

A Financial Relationship may exist whether Covered Personnel are paid directly or whether compensation is routed through another legal entity, such as a limited liability company or non-profit organization.

Covered Personnel are required to report Financial Relationships at the time of any proposed activity covered under the terms of this Policy. Such arrangements may be subject to scrutiny under healthcare fraud and abuse regulations. Failure to disclose Financial Relationships as required under this Policy may result in disciplinary action up to and including dismissal, consistent with UNCHCS and University policies, as applicable.

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 UNCHCS Policies. Financial information reported under this Policy is protected as confidential personnel information. 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.

B. Purchasing Contracts with Vendors

Contracting with Vendors on behalf of the UNCHCS or SOM must be accomplished through the appropriate Purchasing Department. Covered Personnel are generally prohibited from participating in the procurement negotiations with any Vendor with whom such Covered Personnel have a personal interest, a Financial Relationship or other 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 Financial Relationship(s) to those whom they are advising.

C. Educational Activities

Covered Personnel must adhere to the Accreditation Council for Continuing Medical Education (“ACCME”) Standards for Commercial Support guidelines, the Accreditation Council for Graduate Medical Education (“ACGME”) guidelines, and other University or UNCHCS Policies when organizing, holding or presenting an Educational Activity, whether or not credit is awarded. 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 gifts to attendees. Vendors may however make an unrestricted donation or educational grant to the SOM or UNCHCS that the relevant department or unit may choose to use in support of an Educational Activity.

Other Learning Activities

Meals provided during webinars and other Educational Activities in which credits applicable to licensure maintenance (e.g. CME, CLE, CNE, CPE, etc.) that are provided in connection with such activities and are included as part of the event registration or as part of the relevant licensing board’s membership dues are acceptable.

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 UNCHCS or SOM 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 supervisor or designee. Educational materials, such as textbooks or medical journals which benefit patients, students or trainees may be provided by a Vendor to the UNCHCS or SOM, if such materials serve a genuine educational function. No promotional material or product information from the Vendor may be attached to any such item.

UNCHCS and SOM departments may sponsor educational events and solicit financial support from Vendors after advance approval is received from their supervisor and the UNCHCS Compliance Office and/or SOM Dean’s Office. Once approved, the sponsoring department may charge fair market value to participating Vendors for tables to offset the cost of the event in addition to meeting the following conditions:

1. The support is unrestricted with respect to content, topic, and speaker;

2. The support is made at a divisional or departmental level for general educational purposes and not for the benefit of individual faculty members;
3. Support is in compliance with all applicable Accreditation Council for Graduate Medical Education (ACGME) and/or Accreditation Council for Continuing Medical Education (ACCME) standards; and
4. No trinkets, gifts, promotional material, free samples, or other marketing materials are available at the educational event. Only educational materials may be distributed at an educational event.

The sponsoring department is responsible for ensuring that the Vendor(s) abide by all policies and restrictions during the event. The event information should note that the UNCHCS and/or University's acceptance of any such Vendor sponsorship does not constitute expressed or implied endorsement of any particular Vendor's product or service.

E. External Professional Activity

Through certain external professional activity opportunities, Covered Personnel may apply their specialized knowledge and clinical, teaching, research and administrative expertise, thereby contributing further to society. These activities are encouraged if they comply with the applicable policies of the UNCHCS and the University and do not create an unmanageable conflict of interest, as defined by each organization.

Submission of proposed External Professional Activities by the Covered Personnel are required whether Covered Personnel are compensated directly by the outside entity or paid through another legal entity, such as a limited liability company or a non-profit organization. Even if Covered Personnel direct any compensation to be donated or paid directly to UNCHCS or the University, review of the proposed activity is required. Such proposed activities will be reviewed by the UNCHCS and SOM under their respective processes and/or policies; they will also be reviewed for compliance with this Policy.

It is understood that there may be changes in External Professional Activities during a given academic/fiscal year. As applicable under the relevant UNCHCS or SOM process, Covered Personnel are responsible for submitting a new approval request that addresses any such changes, including changes in the amount of time or compensation involved, in advance where possible and not later than thirty (30) days after Covered Personnel learn of the changes related to the External Professional Activities. Failure to comply with these requirements may result in disciplinary action up to and including dismissal, consistent with applicable UNCHCS and University policies.

The UNCHCS and the SOM agree that the following conditions apply when any proposed External Professional Activity involves a Vendor and the Covered Personnel:

1. The proposed activity, including projected compensation, must not be excessive;
2. External Professional Activities must not interfere with the employment obligations of the Covered Personnel;
3. Any honoraria, travel reimbursement, meals or other hospitality associated with the external activity must be reasonable and consistent with the legitimate clinical, educational, administrative or scientific purpose of the activity;
4. Covered Personnel must retain discretion to provide objective commentary or advice based on their professional judgment when delivering the external activities;

5. Covered Personnel must articulate to Vendor and to any other audience that they are conducting such activities in their individual capacity and their views do not necessarily reflect the views of the UNCHCS or University;
6. The external activity may not, in any manner, create an express or implied endorsement by UNCHCS or University of the Vendor's items, supplies, products or services;
7. Covered Personnel may not use UNCHCS or University resources for External Professional Activities. Such UNCHCS or University resources may include facilities, administrative offices, work product, results, materials, property, records, the institutional IRB, the assignment of work to students, residents or trainees, or the use of institutionally licensed software or information developed with institutional funding or other institutional support, except as otherwise reviewed and allowed under other related UNCHCS or University policies. Covered Personnel should seek guidance from their department manager for any clarification.

This Section does not apply to services provided under an authorized institutional contract between a Vendor and the UNCHCS or the University.

UNCHCS Specific Process:

Covered Personnel employed by the UNCHCS may engage in and be compensated for an External Professional Activities, including consulting and related travel arrangements, that are not part of their employment *only if*:

1. The Covered Personnel has disclosed to their immediate supervisor the proposed activity, including the amount of compensation they expect to receive from the proposed External Professional Activity at least ten days prior to the activity;
2. The supervisor determines that any External Professional Activity relationships, including projected compensation, are not excessive;
3. The supervisor determines that such activities will not interfere with or inappropriately influence the employment obligations of the affected Covered Personnel;
4. The supervisor otherwise approves of the activity; and
5. The terms of the agreement for the External Professional Activity meet the standards of this Policy and this activity is not prohibited by another related policy

University SOM Specific Process:

Covered Personnel at the SOM may be permitted to engage in an External Professional Activity provided the activity meets the standards and process of:

1. The University Policy on External Professional Activities: Faculty and EHRA Non-Faculty;
2. The University Policy on Individual Conflict Commitment;
3. This Policy; and
4. The activity is not otherwise prohibited by another related policy (e.g. in contravention of the moonlighting restrictions of the UNC Faculty Physicians Health Affairs Code)

Covered Personnel should start the disclosure process with submission of the External Professional Activity for Pay form. Once reviewed by the applicable individual within the department or unit under relevant policies, the form will be routed to the Dean's Office in the

SOM for additional review. The Covered Personnel will receive an email stating the outcome of the reviews. The External Professional Activity for Pay may be subject to review under related policies, such as the University Policy on Individual Conflicts of Interest.

F. Ghostwriting, Speakers' Bureaus and Speaking Engagements

Covered Personnel are not allowed to engage in Ghostwriting or Speakers Bureaus under any circumstances.

Covered Personnel may be allowed to participate in "speaking engagements" compensated by a Vendor, whether as an External Professional Activity or an institutional activity, provided that:

1. The Covered Personnel are not supporting a Vendor product or service but merely participating as a subject matter expert within their field of expertise;
2. The Covered Personnel retains full editorial control and authority over the content of the presentation;
3. 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;
4. The content of the lecture is based on best available evidence and reflects a balanced assessment of the current science and treatment options;
5. The Covered Personnel discloses at the beginning of the presentation all funding and editorial relationships with the Vendor(s), including disclosure of any Vendor sponsorship of the speaking engagement and receipt of honorarium and/or travel reimbursements for providing the presentation to the program attendees;
6. The slides do not contain any logos or names of the Vendor(s) that sponsored the speaking engagement, except as required for the foregoing disclosures; and
7. In the estimation of the supervisor authorized to approve the speaking activity, as applicable under UNCHCS or SOM policy, 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 to influence the content of the presentation, unless the edits requested by the Vendor are solely to protect its confidential or proprietary information (e.g. removal of content that disclose a not-yet-patented invention). Review of the presentation by the Covered Personnel's supervisor may be required, in the reasonable discretion of the supervisor, prior to the Covered Personnel making any presentation at the request of a Vendor.

G. Gifts

Covered Personnel may not receive gifts of any nature or 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 or for a Vendor.

This prohibition includes gifts to the Family Members of Covered Personnel and to legal entities, such as limited liability companies, through which Covered Personnel might engage in consulting or other external professional activities.

H. Meals and Other Hospitality

Covered Personnel may generally not accept meals or other hospitality from Vendors. Under no circumstances may Covered Personnel accept complimentary tickets to sporting or other events from a Vendor. 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.

Covered Personnel may accept meals or hospitality from Vendors only in the following circumstances:

1. Meals or receptions 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 or professional association meetings and conferences where meals are served to all registered attendees);
2. Meals provided in connection with off-site activities as part of approved an External Professional Activity (as provided in Section III.E above);
3. Materials provided by the organizers of a professional meeting that are available to all attendees at registration, provided the meeting is conducted under national continuing education accreditation body guidelines (e.g., a tote bag provided to conference attendees at check-in).
4. Notwithstanding Section G of this Policy, small gifts or opportunities for prize drawings on-site at UNC Hospitals, as approved by Employee Recreation & Wellness or Volunteer Services, may be permitted in the lobby of UNC Hospitals. Advance approval by the sponsoring office (i.e. Employee Recreation & Wellness or Volunteer Services) must be obtained if the Vendors would like to distribute small gifts (limited to items that have a relatively trivial or de minimis value) or offer a "drawing" for prizes. 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 obtaining approval of any such gifts in advance of the activity and responsible for ensuring that the Vendor abide by all policies and restrictions during the time covering the Vendor's activities on the premises. Vendors may not offer food or health assessments of any kind in this setting.

I. Vendor Site Visits for Training, Possible Research or Evaluations

Covered Personnel may not directly accept reimbursement or sponsorship for travel and expenses for site visits for training, as a preliminary visit to discuss University research, or to evaluate a product or service.

Vendor sponsored visits by Covered Personnel to Vendor sites for training or potential research are acceptable if the cost of such visits is itemized in the quotation and included in a signed final contract with the UNCHCS or University, as applicable. Reimbursement should be requested through the appropriate UNCHCS or University office.

UNCHCS and University Covered Personnel may make site visits to evaluate a product or service at the Vendor's expense, provided that:

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1. All arrangements related to site visits, including selection of participants, duration of the visit, selection of travel method and accommodations, are made in advance and 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.

J. Research, including Sponsored Projects

All research activities, including but not limited to the use of investigational drugs must be conducted pursuant to University or UNCHCS 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, whether externally sponsored (funded) or supported by internal funds. UNCHCS 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 when involved in University research projects (see Section II C: Applicability of Other UNCHCS, UNC Hospitals, and University Policies for a link to the complete Policy). Promotional activities by Vendors may not be performed under the guise of research.

K. Charitable Events

Invitations to local charitable or fundraising events (charity auctions, benefits dinners and golf outings) from non-pharma Vendors may be acceptable upon review and approval by the UNCHCS Compliance Office and/or SOM Dean's Office if all the following conditions are met:

1. Acceptance may not be used to influence decision-making, to induce referral of patients or the ordering of a service or supply, and cannot take into account the volume or value of referrals, purchases or business generated;
2. The event is solely for the benefit of the UNCHCS or the University or another bona fide charitable entity whose mission is related to, complementary to, or otherwise compatible with UNCHCS and/or the University;
3. Advance approval by one's supervisor is included in the request to the reviewing office;
4. Any additional gifts beyond the participation or attendance of charitable event must be declined; and
5. Limitations on the number of invitations may be made if such invitations become excessive.

L. Donations/Gifts from a Vendor

Beyond those unrestricted donations permitted under Section III.G, Vendors generally may provide unrestricted donations to a UNCHCS or SOM 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, with reference to the department name when making donations.

M. Policy Violations

Covered Personnel who are aware of potential violations of this Policy should report those allegations to the University or UNCHCS Compliance Office, University Counsel, or to University or UNCHCS Compliance Hotline. Alleged violations of this Policy shall be investigated by the UNCHCS 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/or the UNCHCS. In addition to any sanctions specifically provided herein, Covered Personnel found to have violated this Policy may be subject to disciplinary action up to and including dismissal.

N. Contacts

Please contact the UNCHCS Compliance Office or SOM Dean's Office, as applicable, for any questions related to this Policy.

III. Original Policy Date and Revisions

Dec 2010

Revision October 2013

Revision June 2014

Revision July 2017