Interactions between College of Medicine Faculty, Staff & Trainees and Health Care Vendors

Policy Principles

The College of Medicine adheres to the following principles when its full and part time faculty, staff, and trainees interact with health care vendors - vendors representing pharmaceutical, biotechnology, nutritional supplement, home health agencies/companies etc. Volunteer faculty members are strongly encouraged to adhere to the principles listed in this document.

• Academic health centers are the proper site and instrument for modeling professional behavior for faculty, staff, and trainees.
• Disclosure of sources, distribution and use of external funding of academic activities is essential.
• Faculty, staff, and trainee activities off-campus and/or off-hours reflect on the integrity of the University, especially when titles and affiliations are cited in slides, announcements or programs.
• Direct marketing activities, on behalf of pharmaceutical or medical instrument firms by our faculty, are discouraged, especially when presented in the guise of providing medical education.
• Conflict of interest, which has particular implications for our relationships with representatives of health care vendors, continues to be a concern in our day-to-day professional lives. Interactions with health care vendors should be conducted so as to avoid or minimize conflicts of interest.

Purpose. The purpose of this policy is to establish guidelines for interactions between industry representatives and the College of Medicine faculty, staff and trainees consistent with the principles listed above.

Scope. This policy applies to interactions between COM faculty, staff, and trainees with health care vendors whether on-campus or off, and includes interactions in support of clinical care, education and training, and research.

Policy. Appropriate interactions between industry representatives and our faculty, staff, and trainees (either on- or off- campus) include but are not limited to the following:

• Marketing of pharmaceutical products, devices and equipment
• Training on devices and equipment
• Development of devices, medications and other agents
• Educational support of faculty, house officers, and trainees
• Continuing medical education programs
• Research

Interactions with industry representatives may create conflicts of interest that could compromise patient safety, data integrity, academic integrity or reputation of faculty, staff and trainees, or the College. When conflicts of interest do arise, they must be declared and addressed appropriately as described in the attached procedures.
Interactions between College of Medicine Faculty, Staff & Trainees and Health Care Vendors – Procedures

1. Interactions between COM faculty, staff, and trainees with medical vendors whether on-campus or off. Vendors are not permitted on-campus without proper identification and prior approval from a faculty member or non-faculty manager. Vendors will be allowed to provide medication samples for the use of patients, but must follow standard Nebraska Medical Center pharmacy procedures MS02 and MS40. (MS02 – Drug and Nutritional Samples) and (MS40 – Pharmaceutical & Nutritional Company Representatives).

Approved interactions include, but are not limited to College of Medicine initiated educational events, in-service training, and individually arranged meetings in private offices (at individual discretion).

a. Unearned income (food, gifts, etc.) from Vendors. The College of Medicine discourages all unearned contributions from health care vendors (> $25)

i. Unrestricted educational grants. Unrestricted educational grants from vendors are acceptable but must be given directly to the department involved and not directly to an individual. The department will distribute to the intended audience with acknowledgement of the vendor (a one sentence thank you to _____company).

ii. COM faculty, staff, and trainees may not accept funds directly from industry for the purpose of attending conferences or meetings in a passive capacity. The Federal Anti-Kickback statute prohibits acceptance of unearned income and other remuneration from health care vendors when one intent may be to induce purchases or prescribing of their products.

b. Earned Income from Vendors. COM faculty, staff and trainees shall not seek or accept anything of value (> $25) from health care vendors except under the following conditions.

i. Active participation in educational programs/consultations, etc. Individual faculty members must comply with UNMC policies with respect to outside activities, including consulting. The “Application for permission to engage in professional activity outside the University” must be filled out and approved by the department chair. (See: UNMC Outside Employment Policy 1049) Generally, up to two working days per month can be devoted to outside activities without prior Regental approval but the “Permission to engage” form must be filled out. See “Permission to engage” form

Examples of cases where “Permission to engage” should be filled out include (but are not limited to): honoraria, travel expenses to a pharmaceutical company workplace, serving on a pharmaceutical company board, utilizing university facilities, expert witness, industry consultant, etc. See “Questions and answers regarding “Permission to Engage in Professional Activity Outside the University” See following excerpt from Questions and answers:
What are some other common examples of cases where I should submit the permission form?

- Honoraria for speaking/consulting activity at the workplace of a pharmaceutical company
- Payment of expenses for travel to a pharmaceutical company workplace
- Serving on a Scientific Advisory Board or Governing Board of a pharmaceutical company
- Recurring and major use of university facilities and resources (sending multiple consultation-related e-mails, letters, packages or making multiple calls; copying at University cost; assigning a secretary/technician to support your consulting related work)
- Paid professional activities: Expert witness; running an editorial office at the University, industry consultant

Are there Professional Activities that do not require submission of the form?

Some areas of professional activity do not require submission of the form. It is not possible to provide a comprehensive listing but the following may serve as a guide to reduce unnecessary paperwork. If in doubt, call the Compliance Office (559-6767). The form does NOT need to be submitted for:

- Honoraria for speaking engagements at professional meetings or in other academic settings
- Payment of expenses for travel to professional meetings, CME sessions, study sections, etc.
- Serving on the Advisory Board, Editorial Board, etc., for a professional organization, journal or academic institution
- Royalties for books or similar products of your academic professional activity
- Incidental and minor use of university facilities and resources (receiving e-mail or calls, library access, etc.)
- Unpaid volunteer professional activities

In general, approval will only be given for those educational events or other activities that are considered to be well balanced and non-biased. Specific evidence of balance and lack of bias must be documented with the “Permission to engage” form before departmental and university approval is provided.

ii. Disclosure of Interest. All faculty, staff, trainees, or guest speakers giving presentations at educational events, including journal clubs and on-campus lectures, must disclose potential conflicts of interest at the time of their presentation. The source of
speaker funding for the presentation should be specifically disclosed as well as other financial ties to industry that could be perceived as conflicts of interest.

Individuals taking a direct role in equipment or drug procurement decisions on behalf of UNMC, or affiliated hospitals such as The Nebraska Medical Center, must disclose any potential financial conflict to the purchasing unit or decision making committee.

iii. **Reimbursement of Expenses.** COM faculty, staff and trainees may accept reimbursement of travel, meals and other expenses for presenting research findings at a meeting or consulting, provided that the expenses are reasonable in relation to the services provided and the Permission to engage form was properly submitted and approved.

### 2. Research: Vendor-sponsored studies

a. **Disclosure of Interest.** COM faculty, staff and trainees participating in vendor-sponsored research shall disclose any financial interests with the sponsor pursuant to the UNMC Research Conflict of Interest Procedures contained in UNMC Policy 8010, “Conflict of Interest”.

b. **Publications**

   i. **Ghost writing.** Individuals are prohibited from publishing under their own name articles that are written in whole or in part by industry employees without the faculty member's input or collaboration.

   ii. **Disclosure of Interest.** In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines (http://www.icmje.org/) and the respective journal’s disclosure requirements.

c. **Supervisory Responsibilities.** Faculty with supervisory responsibility for trainees or staff should ensure that conflicts or potential conflicts of interest do not affect their supervision of the trainee or staff member.

### 3. Training.

All COM faculty, staff and trainees shall receive training regarding potential conflicts of interest in interactions with industry. The department chair and/or program director will determine the frequency and type of training for faculty, trainees and staff depending on the options available. [The COM will help to identify resources for this training].

### 4. Compliance.

Compliance with the above procedures is mandatory. The department chairperson will remain responsible for direct implementation of this policy. Issues related to noncompliance must be reported to the dean or designee for review and appropriate action.

Questions/clarifications regarding this policy? Call Sheila Wrobel, UNMC Compliance Officer at 559-6767 for further information.

Approved – Faculty Council 2/14/08

Implemented - July 1 2008