



University of Kentucky / UK HealthCare Policy and Procedure	Policy # A01-TBD
Title/Description: Code of Conduct Addendum	
Purpose: To provide guidelines for conduct of faculty, staff, students and house officers to comply with applicable law and to avoid conflicts of interest.	

Policy

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Policy

Those acting on behalf of the University of Kentucky must endeavor to conduct business in a manner that facilitates the delivery of quality and efficient health care and to act in accordance with recognized legal and ethical standards aimed at preventing conduct that may inappropriately influence their judgment. This Code of Conduct Addendum reflects the law, regulations, and official published guidelines that are in effect at the time of its adoption. In the event of a conflict between this Code of Conduct Addendum and subsequent more restrictive regulations or law, the more restrictive regulation or law will control.

This Code of Conduct Addendum applies to all University members acting on behalf of the University of Kentucky with respect to any of its Healthcare-Related activities; such members are referred to in this Code of Conduct Addendum as “University Healthcare-Related members.”

“University members” is defined in Part I.D.2 of the Governing Regulations, to include “trustees, executive officers, faculty, staff, and other individuals employed by the University, those using

University resources or facilities, and volunteers and representatives acting as agents of the University.”

The Healthcare-Related activities of the University of Kentucky include the healthcare delivery, clinical and academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences, and Public Health, their affiliated faculty practice plans, University of Kentucky Hospital, UK HealthCare Good Samaritan Hospital, UK HealthCare Ambulatory Services and related support organizations and programs. The University of Kentucky academic Healthcare-Related activities are pursued through these six colleges. The University of Kentucky healthcare delivery and clinical activities are commonly known as “UK HealthCare.”

In order to avoid even the appearance of impropriety or conflict of interest, this Code of Conduct Addendum applies to all faculty, staff, house officers and students involved in the University of Kentucky Healthcare-Related activities, without regard to an individual’s specific job duties or function. Students within the six colleges and house officers are subject to this Code of Conduct Addendum, because of their involvement, or potential involvement, in clinical or healthcare activities and because of the training value for such students and house officers of compliance with regulations pertaining to the healthcare industry.

This Code of Conduct Addendum supplements the [University of Kentucky Ethical Principles and Code of Conduct](#) by providing guidelines that will assist University Healthcare-Related members in the review and determination of appropriate gifts and benefits from and relationships with vendors. Unless specifically addressed by this Code of Conduct Addendum, the University of Kentucky Ethical Principles and Code of Conduct is applicable. University Healthcare-Related members are strongly urged to consult with their supervisors to review and evaluate specific situations. While this Code of Conduct Addendum provides guidance, and in some instances interpretation, additional guidance is found in other official University and UK HealthCare policies and documents, such as [Governing Regulations](#), [Administrative Regulations](#), [Human Resources Policy and Procedure Manual](#), [Hospital and Clinic Policies](#), [Medical Staff Bylaws](#), [College of Dentistry Policy Manual](#), [Corporate Compliance Policies and Procedures](#), [Behavioral Standards in Patient Care](#), and state and federal law. Neither this Code of Conduct Addendum nor the University of Kentucky Ethical Principles and Code of Conduct apply to any benefit or other value provided to UK faculty or staff from funds collected by Kentucky Medical Services Foundation, Inc.

University Healthcare-Related members who fail to comply with this Code of Conduct Addendum can be subject to disciplinary action in accordance with University policy and procedure. University Healthcare-Related members failing to act in compliance with this Code of Conduct Addendum will be considered to be acting outside the scope of their employment and assigned educational duties and could be personally liable should government intervention result.

As used in this Code of Conduct Addendum, “vendor” refers to any person or entity that supplies a commodity or a service to the University. Vendors also include persons or entities that wish to supply a commodity or service to the University.

Gifts and Benefits

“Gifts and Benefits” include, but are not limited to anything of value provided at no charge or at discount such as: drug samples for personal use, snacks and meals, printed and electronic

medical books, supplies and equipment, payment for travel to and/or attendance at meetings, and participation in online vendor sponsored continuing medical or other professional education, loans, cash, gift certificates, services, prizes, art objects, transportation, use of a vehicle or vacation facility, stocks or other securities, participation in stock offerings, home improvements, and tickets to sporting and cultural events. The potential list is endless – these are only intended as examples. Gifts do not include reimbursement for reasonable business expenses paid by faculty practice plans or other University of Kentucky related organizations.

In accepting any gift or benefit, the following guidelines must be observed:

1. University Healthcare-Related members may not accept gifts or other benefits that take into account the volume or value of referrals, purchases, or other business generated.
2. University Healthcare-Related members may not accept gifts or other benefits in exchange for prescribing certain products or services, or to induce referrals.
3. University Healthcare-Related members may not accept gifts or other benefits that could be perceived as an attempt by a vendor to interfere with their independent judgment.
4. Discounted goods and services, or those that eliminate or reduce an expense that would have otherwise been incurred, are also considered gifts under this Code of Conduct Addendum.
5. University Healthcare-Related members may not accept gifts or benefits of little, nominal or no measurable value (for example, pens, notepads, or similar promotional or advertising items with or without company logo) offered or provided by any vendor representative.
6. University Healthcare-Related members may not accept from a vendor items intended for the personal benefit of the recipient (for example, golf bags, tickets to sporting or entertainment events, sponsorship of departmental parties or social events).
7. University Healthcare-Related members may not accept perishable or consumable gifts from a vendor, including without limitation holiday gift baskets or floral arrangements.
8. University Healthcare-Related members may not accept cash or cash equivalents (for example, checks, gift certificates, and stocks) from any vendor.
9. University Healthcare-Related members may not accept gifts intended to be passed on to patients for their use. Federal law prohibits offering or transferring to a Medicare or Medicaid beneficiary anything of value that is likely to influence the patient's selection of a particular provider or supplier.
10. Gifts that are not prohibited may be accepted by the University in accordance with Office of Development policies and procedures.
11. University Healthcare-Related members may not accept snacks or meals provided or supported by any vendor on any occasion either onsite or off-site and whether on or off duty except meals provided in connection with an accredited continuing education program. In addition to any other accreditation requirement, the following guidelines must be followed:
 - (a) The presentation must be educational and unbiased in content.

- (b) The presentation must have independent value by an authoritative speaker.
 - (c) The meals must occur only occasionally.
 - (d) The meal must be modest by local standards.
 - (e) The meal must occur in a venue and manner conducive to learning and discussion.
 - (f) Spouse or other guest attendance is not appropriate.
 - (g) Meals in connection with presentations that are strictly for sales or marketing purposes may not be accepted.
 - (h) Take out meals or meals provided outside the presentation may not be accepted.
 - (i) Entertainment or recreational events associated with the presentation may not be accepted.
12. University Healthcare-Related members may not accept gifts of entertainment. This includes items such as tickets to performances and sporting events, or use of a vacation house. The only exception is participation by a University Healthcare-Related member in an event that takes place solely to benefit a bona fide charitable organization (for example, Kentucky Children’s Hospital, American Heart Association, American Cancer Association) such as a golf scramble or dinner dance. The entertainment must be limited to the activity that is the subject of the event and invitations to such events should be accepted infrequently.

Promotion of Products and Site Access by Vendor Representatives

Pursuant to [Section B-2 of the University of Kentucky Business Operations Manual](#), all purchasing shall be conducted in accordance with the Model Procurement Code. Further, purchases and contracts shall not be made with an employee of the University of Kentucky for any item of supply, equipment, or service, nor may an employee have any interest, directly or indirectly, in any purchase made by the University of Kentucky. Purchases for the University are made for the purpose of meeting program requirements of the various units. [Hospital Policy HP01-31](#) provides specific guidance for vendors with respect to hospital purchasing and the presence of vendors within the hospital as required by The Joint Commission.

1. If a vendor wishes to introduce a non-pharmaceutical surgical product or device into this institution that has not been approved by the appropriate overseeing committee for general use within the University or UK HealthCare in particular, the vendor representative should contact the appropriate faculty or senior staff, (i.e. not an individual in training), to have him or her evaluate the request and, if justified and valid, present the appropriate request to the corresponding device or product evaluation and selection committee of the University or UK HealthCare. Students or house officers should never be directly approached by a vendor about a product that has not yet been evaluated and approved for use in the University.
2. If a vendor wishes to introduce a pharmacological and biological agent into this institution, the exact same process must be followed, and the request, if appropriate, will be presented to the Pharmacy & Therapeutic committee. Direct unsupervised contact between pharmaceutical representatives and students or house officers to promote a drug

that has not been evaluated and approved by the Pharmacy & Therapeutic committee is not allowed in this institution.

3. Products, devices, and drugs not yet approved for use in the University can and should be discussed with students and house officers as part of the formal educational efforts of the corresponding departments or divisions. These discussions, however, must be initiated, designed, directed, and supervised by the appropriate senior staff or faculty. Under no circumstances should a vendor dictate the content or provide paid speakers for this purpose. Unsupervised “educational lunches” for students and house officers initiated and sponsored by Industry are prohibited whether on-campus or off-campus.
4. Whenever a new product, device, or pharmacological agent is approved for general use or trial in any University Healthcare-Related activity, education and training of the appropriate faculty and staff shall be organized and supervised by a University Healthcare-Related faculty or staff member. These educational/training sessions should be done in a formal and structured fashion that allows ample opportunity for discussion and critical appraisal. Students and house officers can greatly benefit from participating in this process. A vendor can participate in these activities and provide educational resources, including literature, technical people, or expert users, but only with the specific and direct approval of the faculty or staff member coordinating this process.
5. Access by vendors to University Healthcare-Related faculty and staff shall be limited to non-public, non-patient-care areas, and shall only occur by appointment or invitation from faculty or senior staff. Involvement of students and house officers in such meetings is encouraged but should only occur under the direct supervision of faculty or senior staff personnel.
6. Vendors must register appointments they have throughout UK HealthCare.
7. When the presence of a vendor in patient care areas is deemed advisable and necessary, the attending physician must assume responsibility for the vendor’s appropriate presence and performance in the clinical area. This does not mean, however, that the vendor does not remain fully responsible for his or her presence and performance. This activity must be guided by applicable law and UK HealthCare policies governing patient privacy and confidentiality, informed consent, and quality patient care. There must be written documentation of the vendor’s competence and qualifications to perform whatever tasks are assigned to this individual, appropriate background checks, and there must be clear documentation that his or her presence is essential for safe and efficient patient care. Finally, as part of the informed consent process, the patient must be informed of the presence, purpose and role of the vendor representative.
8. Under the circumstances defined above in subsection 7, no gifts of any value, including meals and snacks, and no promotional activities of any type, can be given or take place in association with the presence of a vendor representative in the patient-care clinical area.

Membership on Drug, Device and Equipment Evaluation and Selection Committees

1. Persons who serve on Pharmacy and Therapeutic/ Value Analysis/ Technology Assessment committees shall fully disclose all relations with any vendor, without exception, at least once a year and whenever relevant changes occur. Full disclosure must include without limitation, speaker bureaus, occasional speaker engagements, stock

ownership, grants or educational support received or being applied for, research involvement with any drug, device or equipment, consulting work, patents, etc., as well as immediate family member relations. Disclosure shall be made on a form developed for such purpose by the University and shall be made to the Vice President for Health Care Operations. Persons whose relations with a vendor create conflicts in serving on such committees may be removed from such committees.

2. When an item is discussed in which a member has a potential conflict of interest based on a financial or research or investigational relationship with the involved vendor, the nature of the relationship shall be disclosed to the committee at that time. That individual may participate in the discussion at the discretion of the chairperson of the committee but shall excuse himself or herself from the final decision making.

Sponsorship of Continuing Education Meetings, Professional Meetings, and other Scientific and Education Conferences

Industry organizations may not directly or indirectly subsidize a University Healthcare-Related member's attendance at a conference or meeting. This prohibition includes conference registration fees, travel, meals, entertainment, accommodations, and the attendee's time for attending the conference. An organization may subsidize a conference or meeting by providing a subsidy directly to the conference sponsor who in turn can reduce the conference fee for all attendees.

Modest meals, such as lunches, refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate. In these cases, the meals or receptions should be modest and conducive to discussion among attendees, and the amount of time at the meals or receptions should be subordinate to the amount of time spent at the education activities of the meeting.

1. Vendor initiated and conducted conferences, seminars and other meetings shall not be permitted on-campus.
2. Only properly accredited continuing education activities may be funded or supported by a vendor, if desired, and national guidelines regarding commercial funding for continuing education programs must be explicitly followed in all cases.
3. All commercial support for educational activities shall be requested by, and given to, a College, Department, Division, or other similar group, and not to any one specific individual.
4. Other than properly accredited (ACCME or other) continuing education activities, there shall be no direct sponsorship of institutionally initiated and conducted conferences and meetings.
5. Under no circumstances shall vendor representatives be allowed to select the topic or the speaker for any educational activity.
6. University Healthcare-Related members are discouraged from attending vendor initiated and conducted non- accredited off-campus meetings that are advertised as continuing education.

Participation in Vendor Sponsored Research

University Healthcare-Related members who participate in vendor sponsored research must abide by the [University of Kentucky Research Conflict of Interest and Financial Disclosure Policy](#).

Publication of Research Initiated, Supported, or Sponsored by Vendors

University Healthcare-Related members who author or co-author publications related to research sponsored by or initiated by vendors must comply with the following guidelines:

1. Full disclosure of any possible conflicts of interest on the part of all authors.
2. Full disclosure of sponsor's role in the study and writing of the paper.
3. The author(s) must have substantial say in trial design.
4. The author(s) must have access to raw data.
5. The author(s) must be responsible for data analysis and interpretation.
6. The author(s) must retain the right to publish results without consent or prolonged review by the sponsor.

Ghostwriting

“Ghostwriting” refers to the practice in which someone else has provided written material that is then credited or attributed to someone other than the original writer. In this Code of Conduct Addendum, it refers to an University Healthcare-Related member adding his or her name to a manuscript that was conceived, designed, and mainly written by someone else, (often a vendor representative or a proprietary research organization under contract with a vendor) which the University Healthcare-Related member played no essential role in its development and writing. It excludes manuscripts written by others within the University Healthcare-Related member's department/division (i.e., faculty, staff, students and house officers) for whom the University Healthcare-Related member has a supervisory role and played an advisory role in the development of the manuscript, carefully scrutinized the content and assured the accuracy of said manuscript. It also does not apply to the transparent writing in collaboration with a vendor investigator, medical writer or technical expert.

1. University Healthcare-Related members shall not allow their names to be listed on papers that were ghostwritten as defined above.
2. The source or author of all content of an article must be documented in all published manuscripts. Although criteria for authorship vary, authorship qualification should be based on meeting the following criteria:
 - (a) The person substantially contributes to conception and design, or acquisition of data, or analysis and interpretation of data;
 - (b) The person drafts the article or revises it critically for important intellectual content;
 - (c) The person approves final version to be published; and
 - (d) The person agrees to be named as an author.

Conference Faculty; Speakers Bureaus

From time to time, vendor representatives ask University Healthcare-Related members to speak at or otherwise serve as faculty or presenters at conferences or meetings. Speaker bureau activity includes conferences and meetings that are arranged by a vendor who selects the speakers and provides them with training on the vendor's products and compliance with FDA regulations and assures that the speakers provide a valuable service to the vendor.

1. University Healthcare-Related members shall not participate in vendor speakers bureaus.
2. University Healthcare-Related members may participate as occasional sponsored speakers in non- accredited vendor sponsored FDA-regulated "educational" programs only if the following criteria are satisfied:
 - (a) He or she should be convinced that the activity is designed to promote evidence-based, unbiased clinical care and/or advances in scientific research.
 - (b) The financial support of any vendor should be prominently disclosed.
 - (c) The lecture content and slides should be determined by the University Healthcare-Related member and reflect a balanced assessment of the current science and treatment options.
 - (d) The University Healthcare-Related member must make clear that the views expressed are those of the speaker and not those of the University or UK HealthCare.
 - (e) Compensation for travel, expenses and honorarium may not exceed the fair market value of the services provided and must comply with this Code of Conduct Addendum for such compensation. For clinical Faculty, reimbursement for expenses is generally not considered income subject to applicable practice plan agreements, and honoraria may be excluded depending upon the specific college's practice plan; however, such income remains subject to University policies and regulations. Reimbursement may not be accepted for expenses of a spouse, family member, or other traveling companion.
 - (f) Such activity shall be considered consulting and must comply with the guidelines applicable to consulting described below.

Consulting Arrangements

All University Healthcare-Related members will abide by [AR II-1.1-1, Consulting and Other Overload Employment](#), [Human Resources Policy and Procedure Number 18.0 Outside Employment](#) and this Code of Conduct Addendum with respect to all outside employment and consulting arrangements. In addition, University Healthcare-Related members that participate in a faculty practice plan must comply with the provisions of the Administrative Regulation pertaining to such practice plan and the applicable College Addendum, thereto.

Consultants who provide bona fide services may accept reasonable compensation for those services and may be reimbursed for reasonable expenses incurred as a result of the consulting relationship if the following guidelines are observed:

1. The arrangement is set out in writing covering all of the following points prior to payment.

2. The written agreement covers all of the services to be provided.
3. The compensation is set out in advance.
4. If the agreement is for periodic, sporadic or part-time services, it must identify the schedule of intervals, precise length and exact charge for such intervals.
5. The term of the agreement is for no less than one year.
6. There is legitimate need for the services.
7. The services are actually provided.
8. The compensation is based on the fair market value of the services provided.
9. The compensation is not determined in a manner that takes into account the volume or value of any referrals or other business generated.

Compensation given for “consulting” for attending meetings or conferences in a primarily passive capacity is inappropriate. Vendor relationships with physicians or other medical providers where compensation is paid for marketing activities such as speaking, research, preceptor, “shadowing” arrangements or time spent listening to vendor representatives marketing their products are suspect, and payment may not be accepted as “consulting” fees, even if the physician is required to perform services such as completing minimal paperwork or accessing a website.

Compensation for any consulting arrangement must be handled pursuant to the applicable practice plan agreements. Consulting agreements must be reviewed by the University of Kentucky Legal Office or Corporate Compliance Office prior to acceptance.

Scholarships

1. Vendor support for student and house officer activities, including travel expenses or attendance fees at carefully selected educational conferences, must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be maintained at the college or department as determined by the dean. Vendors may not earmark contributions to fund specific recipients or to support specific expenses. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for students or house officers to attend conferences or training that have legitimate educational merit. Attendees must be selected by the department/division based upon merit and/or financial need, with documentation of the selection process provided with the request. Conferences that qualify as a “carefully selected educational conference” are in general terms defined by the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations. Approval of particular requests shall be at the discretion of the dean.
2. Vendor support for student and house officer training, tuition, stipend and benefits must comply with all University and UK HealthCare requirements for such funds, including the execution of an approved budget and written gift agreement and be maintained in an appropriate restricted account, managed at the college or department as determined by the dean.

3. Selection of recipients of scholarships or fellowships will be within the discretion of the college in which the student is enrolled or, in the case of house officers, the dean.
4. No quid pro quo shall be involved.
5. These guidelines do not apply to formal research grants supported by vendors.

Training and Site Visits

On occasion UK faculty and staff may be required to travel to other locations in order to view or train on new equipment or systems that are used, intended to be used, or under consideration for purchase for use in a University Healthcare-Related activity. Such travel is only considered legitimate if the product, equipment or training cannot reasonably be brought to the University campus.

The following guidelines must be observed:

1. All site visits must comply with the Commonwealth of Kentucky Model Procurement Code and UK Purchasing rules, and must be arranged in coordination with the UK Purchasing Division.
2. Generally, if the University is evaluating a product or service, the site visit shall be considered an operating expense of the University area which is considering the purchase. All costs related to the site visit will be the responsibility of the University area that visits a particular location.
3. If the University has purchased or has agreed to purchase an item or service, and a site visit or training is included as part of the purchase agreement, it is appropriate for the vendor to pay for the travel, meals and lodging. However, entertainment associated with the travel is not appropriate and the travel, lodging, and meals must be reasonable.

Procedure

Clarifications and Reporting Violations

For additional interpretation, counsel or advice regarding this Code of Conduct Addendum, contact the Medical Center Office of the University Legal Counsel or the Corporate Compliance Office. Reports of suspected misconduct should be made to the Corporate Compliance Office according to the [Corporate Compliance Program's Operating Policies and Procedures](#). Reports must be made promptly, preferably within 24 hours of discovery and may be made directly to the Corporate Compliance Officer at 323-6044, by pager at 1-888-898-1872, or anonymously at 1-877-898-6072. All credible reports will be investigated properly and fully within a reasonable time period.

NOTE: Nothing in this Code of Conduct Addendum is intended to place additional limitations on official gifts and endowments made to the University of Kentucky under University Administrative Regulations. Nor is it meant to prevent industry sponsored health fairs aimed at educating the general public or industry support of nationally accredited continuing education programs for health care professionals through educational grants to the University of Kentucky.

Persons and Sites Affected

Enterprise Chandler Good Samaritan Kentucky Children's Ambulatory Department

Policies Replaced

Chandler HP Good Samaritan Kentucky Children's CH
 Ambulatory KC Other University of Kentucky, Code of Conduct Addendum - Clinical Enterprise Compliance Policy

Effective Date: 7/1/2009

Review/Revision Dates:

Approval by and date:

Signature _____ Date _____
Name Eugene A Hessel, II, Review Team Co-Leader

Signature _____ Date _____
Name Jay Perman, Dean, College of Medicine, Review Team Co-Leader

Signature _____ Date _____
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Signature _____ Date _____
Name Kumble Subbaswamy, Provost

Signature _____ Date _____
Name Michael Karpf, Executive Vice President for Health Affairs

Signature _____ Date _____
Name Lee Todd, President, University of Kentucky