Office of the President June 19, 2020

Members, Board of Trustees:

NOTIFICATION OF CODE OF CONDUCT ADDENDUM AMENDMENTS

Pursuant to University of Kentucky Board of Trustees PR 4, dated March 2, 2004, the Board approved a Clinical Enterprise Code of Conduct Addendum. Per the Board's PR 4, dated April 6, 2004, the Board delegated authority to amend that Addendum as needed, including any revisions required by law, to the University Provost and the Executive Vice President for Health Affairs. Pursuant to the Board's PR 4, this report is to notify the Board of changes to that Addendum as outlined below.

The Addendum was separated into the following five policies:

- Code of Ethics
- Conflicts of Interest
- Industry Representatives
- UK HealthCare Members Interactions with Industry Representatives
- Annual Disclosure of Financial Conflicts of Interest

The following recent updates have occurred to all five policies: (i) titles have been updated to identify the policies as part of the Addendum, (ii) references have been added linking to the other policies, (iii) the Provost's signature has been included and (iv) a definition of UK HealthCare member and its application to the provisions within the policy has been added to align with the Board's original intent.

Additionally, recent edits were made to the following individual policies. For the *Conflicts* of *Interest* policy, a sentence addressing the receipt of gifts by University of Kentucky HealthCare members from patients has been added. For the *Industry Representatives* and *UK HealthCare Members Interactions with Industry Representatives* policies, a definition for industry representative was added and a footnote defining entities from that definition, such as regulatory or accrediting bodies, was included.

This notification is for informational purposes only. No Board action is needed. All five policies are attached.

EXECUTIVE SUMMARY—CODE OF CONDUCT POLICIES JANUARY 15, 2020

BACKGROUND AND GENERAL SUMMARY OF CHANGES:

- The five (5) UKHC Enterprise Code of Conduct policies below are derived from the initial Clinical Enterprise Code
 of Conduct Addendum approved by the UK Board of Trustees (UK BOT) on March 2, 2004 per PR 4. On April 6,
 2004, per PR 4, the UK BOT delegated authority to amend the Code of Conduct Addendum to the EVPHA and
 Provost and required the President to report all amendments to the Code of Conduct Addendum to the UK BOT.
 These changes are to be reported to BOT.
- Titles were updated to identify the policies as part of the Code of Conduct Addendum.
- Reference section was added to the end of all policies hyperlinking to the other Code of Conduct policies.
- Provost signature was added to all policies.
- Definition of a UKHC member was aligned with original UK BOT intent and updated on all polices for continuity. Definition states:

The policy applies to all UK Healthcare Members. For the purpose of this policy "UK HealthCare Members" is defined as University of Kentucky Trustees, UK HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery, and all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care.

SUMMARY OF SPECIFIC CHANGES TO INDIVIDUAL POLICIES:

- A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
 - a. No content changes other than general changes mentioned above.
- A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
 - a. Addition of sentence addressing the receipt of gifts by UKHC members from patients:
 - iii. "Without prior authorization, no UKHC employee shall accept an unauthorized gift, food, or other favor from a patient for whom they have provided care, services, and/or referred services except small tokens of gratitude with an estimated cash value less than \$50 may occasionally be accepted. Contact the Office of Corporate Compliance with questions."
- A01-105, Industry Representatives (Code of Conduct Addendum, Part 3 of 5) and A01-155, UK HealthCare Members Interactions with Industry Representatives (Code of Conduct Addendum Part 4 of 5)
 - a. Addition of industry representative definition and footnote carving out some entities from that definition:
 - ii. Industry representative definition added: For the purpose of this policy, industry representative means any industry representative, vendor, or supplier which does business or is doing business with UK HealthCare, including, but not limited to, a person, individual, proprietorship, firm, partnership, limited partnership, joint venture, joint stocking company, syndicate, business, statutory trust, estate, company, corporation, limited liability company, association, club, committee, organization or group of persons acting in concert that does business or is doing business with UK HealthCare.
 - iiii. Footnote: ¹For purposes of this policy, industry representative shall not include any entity with which UK HealthCare is legally required to interact, such as a licensing, regulatory, accrediting or organ procurement organization, provided the purpose of the interaction is to meet those legal requirements. However, if such entity or its affiliates does business or is doing business with UK HealthCare and is interacting with UK HealthCare members for such business purposes then this policy applies.
- A01-160, Annual Disclosure of Financial Conflicts of Interest (Code of Conduct Addendum, Part 5 of 5)
 - a. No content changes other than general changes mentioned above.



Policy # A01-005

Title/Description Code of Ethics (Code of Conduct Addendum, Part 1 of 5)

Purpose: To set forth the code of ethics applicable to the operations of UK HealthCare.

<u>Policy</u> Procedure

Patient Care

Billing Practices

Resolution of Conflict

Confidentiality

Research Programs

Conflict of Interest

Marketing

Contracting

Corporate Compliance

Other External Relations

Questions

See Also

Persons and Sites Affected

Policies Replaced

Effective Date

Review/Revision Dates

Policy

UK HealthCare has an ethical responsibility to the patients and communities it serves. The mission, vision, and values of UK HealthCare provide a framework for patient care and business practices. This code addresses ethical practices regarding marketing, admission, transfer, discharge, billing, and the resolution of conflicts. In addition, it addresses protection of the integrity of clinical decision-making.

The policy applies to all UK Healthcare Members. For the purpose of this policy "UK HealthCare Members" is defined as University of Kentucky Trustees, UK HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery, and all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care.

Consistent with the mission and vision of UK HealthCare, Living DIReCT¹, and the Behavioral Standards, UK HealthCare values:

- 1. Integrity, honesty, fairness, and ethical behavior in all that we do.
- 2. The constant pursuit of excellence and innovation.
- 3. The contribution of each employee in achieving our overall mission.
- 4. The right of each patient to choose the type and extent of care.
- 5. Caring and sensitivity in all patient interactions.
- 6. Responsible resource management.
- 7. Teamwork, cooperation, and flexibility.
- 8. Differences among people.

Procedure

Patient Care

Patients are admitted, treated, discharged, or transferred based on their clinical needs and without regard to age, ancestry, ethnicity, color, disability, national origin, race, language, religious creed, sex, gender identity or expression, sexual orientation, appearance, socio-economic status, veteran status, physical or mental disability, diagnosis, or ability to pay.

Patients and/or families are involved in all care-related decisions as much as possible. Employees shall inform all patients about the therapeutic alternatives and the risks associated with their care.

Information regarding diagnosis, prognosis, treatment and/or research options, and costs, delivered in language understandable to the patient, is fundamental for informed choice. UK HealthCare shall provide for the protection of those unable to be their own advocate as a result of incompetence or incapacity.

When an individual requests or presents for care, treatment, and services, UK HealthCare is professionally and ethically responsible for providing care, treatment, and services within its capability, mission, and applicable law and regulation. At times, indications for such care, treatment, and services can contradict the recommendations of an external entity performing a utilization review (for example, insurance companies, managed care reviewers, and federal or state payers). If such a conflict arises, care, treatment, service, and discharge decisions shall be made based on the patient's identified needs, regardless of the recommendations of the external agency.

Billing Practices

UK HealthCare shall engage in reasonable billing and collection practices that are compatible with generally accepted standards of ethical business practice and state and federal laws and regulations.

¹ Living DIReCT values: Diversity, Innovation, Respect, Compassion, and Teamwork. See more at: https://www.uky.edu/pe/uk-healthcare-values

Qualified personnel shall be available to assist patients with questions and concerns related to billing issues.

Resolution of Conflict

UK HealthCare shall resolve all conflicts fairly and objectively. This includes any request for change in caregivers that is outlined in policy <u>A08-105</u>, <u>Patient Rights and Responsibilities</u>. If mutual satisfaction cannot be achieved among the principal parties to a dispute, UK HealthCare shall involve the patient representative, Risk Management, UK HealthCare administration, and/or the Ethics Committee for assistance and resolution.

Confidentiality

Patient and other applicable information shall not be shared in an unauthorized manner. Sensitive information concerning personnel and management issues shall be maintained in the strictest confidence and utilized only by those individuals authorized to review and act upon such information. UK HealthCare Members shall control the formal and informal transmission of confidential information of any kind.

Research Programs

The integrity of research programs conducted within UK HealthCare facilities is facilitated through the activities of the Institutional Review Board (IRB). Research efforts shall be free of fraudulent activity and scientific misconduct, and comply with federal, state, and/or local regulations governing the welfare and safety of human subjects and research personnel involved in the studies.

Conflict of Interest

UK HealthCare Member participation in any activity that may conflict with the purpose or objectives of UK HealthCare is prohibited. See policy <u>A01-030</u>, <u>Conflicts of Interest</u>.

Marketing

UK HealthCare shall fairly and accurately represent its care, treatment, and service capabilities to the public.

Contracting

Contracting decisions shall be based on established standards of ethical business practice and seek to maintain quality care in a cost-effective manner.

Corporate Compliance

All UK HealthCare Members shall be educated about and conform to the standards and procedures of the Corporate Compliance Program.

Other External Relations

In all interactions with representatives of external agencies (public or private), special interest groups, or the general public, UK HealthCare Members shall practice honesty, make objective and fair representations, avoid conflicts of interest, and maintain confidentiality of information.

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

See Also

Additional information, definitions, and authorization procedures are outlined in policies and administrative regulation below:

A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)

A01-105, Industry Representatives (Code of Conduct Addendum, Part 3 of 5)

A01-155, Interaction with Industry Representatives (Code of Conduct Addendum, Part 4 of 5)

A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum, Part 5 of 5)

AR 3:9, Consulting and Other Overload Employment Outside the University

Policy # A01-005 Code of Ethics (Code of Conduct Addendum, Part 1 of 5) 4

Persons and Sites Affected Enterprise Chandler Good Samaritan KCH Ambulatory Departments: [UKHC Policy Sites Departments] Policies Replaced Chandler HP01-02 Good Samaritan Kentucky Children's CH Ambulatory KC Other Effective Date: 2/24/2020 Review/Revision Dates: 10/2011;
Policies Replaced ☐ Chandler HP01-02 ☐ Good Samaritan ☐ Kentucky Children's CH ☐ Ambulatory KC ☐ Other
☐ Chandler HP01-02 ☐ Good Samaritan ☐ Kentucky Children's CH ☐ Ambulatory KC ☐ Other
☐ Chandler HP01-02 ☐ Good Samaritan ☐ Kentucky Children's CH ☐ Ambulatory KC ☐ Other
☐ Chandler HP01-02 ☐ Good Samaritan ☐ Kentucky Children's CH ☐ Ambulatory KC ☐ Other
Ambulatory KC Other
Effective Date: 2/24/2020 Review/Revision Dates: 10/2011:
10/7/2015;10/1/2018; 2/24/2020
Approval by and date:
Signature Name Rebecca Scott, Compliance/Privacy Manager, Review Team Leader Signature Name Brett Short, Chief Compliance Officer Signature M. Gwen Moreland, Chief Nurse Executive Signature Angela Lang, Chief Experience & Operations Officer Signature Name Jap Grider, MD, Chief Physician Executive, Interim Signature Name John W. Phillips, Vice President for Ambulators Operations Signature Name College Swartz, Vice President for Hospital Operations Signature Name Mark Newman, MD, Executive Vice President for Health Affairs Signature Name David W. Blackwell, PhD, University of Kentucky Provost Date 5/29/20 Date 5/29/20 Date 5/29/20 Date 5/2/20 Date 5/20 Dat



Policy # A01-030

Title/Description: Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)

Purpose: To provide guidance for UK HealthCare members regarding participation in activities that may be in conflict with the purpose or objectives of the UK HealthCare enterprise.

Policy
Procedure
Questions
See Also
Persons and Sites Affected
Policies Replaced
Effective Date
Review/Revision Dates

Policy

UK HealthCare prohibits participation in any activity that may conflict with the purpose or objectives of the UK HealthCare Enterprise. The policy applies to all UK Healthcare Members. For the purpose of this policy "UK HealthCare Members" is defined as University of Kentucky Trustees, UK HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery, and all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care.

Procedure

- 1. Without prior authorization, no UK HealthCare Member shall:
 - (a) Work as a sub-contractor, vendor, supplier, consultant, etc., for UK HealthCare.
 - (b) Perform a service for an outside "for profit" enterprise that does business with UK HealthCare.
 - (c) Accept an unauthorized gift, loan, food, or other favor from an outside agent that does, or seeks to do, business with UK HealthCare. See policy <u>A01-160, Annual Disclosure of Financial Conflicts of Interest.</u>
 - (d) Accept an unauthorized loan from a patient for whom they have provided care, services, and/or referred services.

- (e) Accept an unauthorized gift, food, or other favor from a patient for whom they have provided care, services, and/or referred services except small tokens of gratitude with an estimated cash value less than \$50 may occasionally be accepted. Contact the Office of Corporate Compliance with questions.
- (c) Disclose or otherwise use confidential UK HealthCare information outside of official job requirements.
- (d) Compete with UK HealthCare, either directly or indirectly, in the purchase or sale of property or property rights.
- (e) Represent another health care institution in any transaction where they or a relative have a substantial interest.
- (f) Act as a representative of UK HealthCare in correspondence or contact with an external agency or person, except as a part of specific job function, unless approved by UK HealthCare Administration or authorized designee.
- 2. UK HealthCare Members and their immediate families shall not::
 - (a) Perform services for UK HealthCare where the UK HealthCare member would have a position of influence.
 - (b) Accept unauthorized gifts, loans, food, or other favors from an outside agent which does, or seeks to do, business with UK HealthCare.
- 3. All UK HealthCare Members shall follow these guidelines:
 - (a) They shall not have any interest or relationship that is prohibited, or might cause a conflict of interest, or give the appearance of a conflict of interest.
 - (b) They shall contact the compliance officer immediately upon becoming involved in any possible conflict of interest. Contact information is located on the Corporate Compliance website.
 - (i) To make a report, staff may use the <u>on-line report form</u> or call the University of Kentucky Comply Line at (877) 898-6072.
 - (ii) The Comply Line is a toll-free number and is staffed by live operators 24 hours a day, seven days a week. This site is managed by a third party company.
 - (c) They shall not divulge or otherwise use any confidential UK HealthCare information for a period of twelve months after leaving UK HealthCare employment.
 - (d) The Executive Vice President for Health Affairs and Chief Physician Executive, in conjunction with the Chief Compliance Officer or designee, shall make all final decisions involving compliance with this policy.

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

See Also

Additional information, definitions, and authorization procedures are outlined in policies and administrative regulation below:

A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)

A01-105, Industry Representatives (Code of Conduct Addendum, Part 3 of 5)

A01-155, Interaction with Industry Representatives (Code of Conduct Addendum, Part 4 of 5)

A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum, Part 5 of 5)

AR 3:9, Consulting and Other Overload Employment Outside the University

Policy # A01-130 Conflicts of Interest 3

Persons and Sites Affected	· · · · · · · · · · · · · · · · · · ·			
☐ Enterprise ☐ Chandler ☐ Good Samaritan ☐ Kentucky Children's ☐ Ambulatory ☐ Department				
Policies Replaced				
☐ Chandler HP01-03 ☐ Good Samaritan ☐ I Ambulatory KC ☐ Other	Kentucky Children's CH			
Effective Date: 2/24/2020	Review/Revision Dates : 8/12/2015; 10/1/2018; 02/24/2020			
Approval by and date:				
Signature Name Rebreek Scort, Compliance Manager, Rev	Date 5/29/20			
Signature Name Brett Short, Chief Compliance Officer	Date 6 - 1 - 20			
Signature <u>Moreland</u> Name M. Gwen Moreland, Chief Nurse Executiv	Date 5/7/2000			
Signature Angela Lang, Chief Experience & Operation	Date 5/7/270			
Signature Smyllva	Date 5/1/220			
Name Jennifer Rose, Chief Administrative Office	-1-12-1			
Signature Name Jay Grider, MD, Chief Physician Executive	Date			
Signature Name John W. Phillips, Vice President for Ambu	Date 6/1/2020			
Name Colleen Swartz, Vice President for Hospita	Date 5-38-30			
Signature Marwellum	Date 5/21/20			
Name Mark Newman, MD, Executive Vice President Signature Name David W. Blackwell, PhD, University of K	Date 6/9/2020			



Policy # A01-105

Title/Description Industry Representatives (Code of Conduct Addendum, Part 3 of 5)

Purpose: The purpose of this policy is to act as guidance for industry representatives in their interactions with UK HealthCare Members. It also sets expectations for behavior when on the premises of any UK HealthCare facility.

Policy

Procedure

Training and Orientation of New Industry Representatives

Registration of Visits

UK HealthCare Issued Name Badges

Industry Representative Access to UK Healthcare Members

Gifts and Meals

Samples

Industry Representatives in Patient Care Areas

Violation of Policy

Gifts, Gratuities, and Entertainment

Questions

See Also

Persons and Sites Affected

Policies Replaced

Effective Date

Review/Revision Dates

Policy

The policy applies to all industry representatives in their interactions with UK HealthCare members. For the purpose of this policy, industry representative means any industry representative, vendor, or supplier which does business or seeks to do business with UK HealthCare, including, but not limited to, a person, individual, proprietorship, firm, partnership, limited partnership, joint venture, joint stocking company, syndicate, business, statutory trust, estate, company, corportation, limited liability company, association, club, committee, organization or group of persons acting in concert that does business or seeks to dobusiness with UK HealthCare .¹ "UK HealthCare Members" is defined as University of Kentucky Trustees, UK

¹ For purposes of this policy, industry representative shall not include any entity with which UK HealthCare is legally required to interact, such as a licensing, regulatory, accrediting or organ procurement organization, provided the purpose of the interaction is to meet those legal requirements. However, if such entity or its affiliates does business or seeks to do business with UK HealthCare and is interacting with UK HealthCare Members for such business purposes then this policy applies.

HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery, and all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care.

Interactions with Industry occur in a variety of on-campus and off-campus circumstances, including marketing of new products, training of new purchases, research support, educational support for trainees and continuing medical education programs. Many aspects of these interactions are very positive and important for promoting the educational, clinical and research missions of UK HealthCare. However, these interactions must be ethical and cannot create conflicts of interest, real or perceived, that could endanger patient safety, data integrity, the integrity of our education and training programs or the reputation of our members and our institution.

Procedure

Training and Orientation of New Industry Representatives

Before their first visit or appointment, all pharmaceutical industry representatives must register with UK HealthCare Pharmacy Services Administration. All other industry representatives must register with UK HealthCare Purchasing. When registering, the industry representative shall complete a computer-based module orientation session and receive a packet of information. The computer training and the packet will include UK HealthCare policies, University of Kentucky purchasing information, information regarding patient confidentiality and current immunization requirements, and agreements stating that the industry representative shall adhere to Behavioral Standards, as well as to American Medical Association and Research & Manufactures of America guidelines. Documentation of completed training will be maintained electronically with Pharmacy or with Purchasing, as appropriate.

Registration of Visits

Industry representatives must sign in on-line with Pharmacy or Purchasing at least 24 hours prior to their scheduled visit. Sign-in information shall include their destination, the individuals with whom they are meeting and the time of each meeting. Failure to sign in will be considered a violation of this policy.

UK HealthCare Issued Name Badges

All industry representatives shall be issued an identification badge for appropriate access. The badge shall include the individuals name and company. Any falsification of this information will be considered a violation of this policy. The badge must be worn on the upper front torso and be visible at all times while the representative is in a UK HealthCare facility. Failure to wear an identification badge will be considered a violation of this policy.

Industry Representative Access to UK Healthcare Members

1. Industry representatives are required to make an appointment in order to meet with a UK HealthCare Member. These appointments must be in non-patient, non-care areas and shall be between the hours of 6:00 am and 5:00 pm, Monday through Friday.

Policy # A01-105 Industry Representatives (Code of Conduct Addendum, Part 3 of 5) 2

2. Industry representatives may not interact directly with students or house officers unless supervised by a UK HealthCare Member.

Gifts and Meals

- 1. UK Healthcare Members may not accept gifts from industry representative regardless of the nature or value.
- 2. Industry sponsored meals or snacks are not allowed unless the meal or snack is in conjunction with an accredited continuing education program and it is offered to all attendees.

Samples

- 1. For polices regarding pharmaceutical samples, see UK HealthCare Department of Pharmacy policy PH-11-11 and UK HealthCare Policy #C06-015.
- 2. All non-drug samples used in a patient care setting shall be registered with and approved by the overseeing committee before use. A valid no charge purchase order number shall be issued by Purchasing. All such products and equipment shall be FDA-approved or have Institutional Review Board (IRB) approval for clinical use.

Industry Representatives in Patient Care Areas

- At the request of the attending physician, an industry representative may be allowed in a
 patient care area. The attending physician assumes responsibility for the representative
 and must be present with the representative at all times. The interaction with the patient
 must be guided by UK HealthCare policies governing patient privacy and confidentiality,
 informed consent and quality patient care.
- 2. At the request of a surgeon, an industry representative may be allowed in an operating room or other procedure areas to provide technical support.
 - (a) The special consent signed by the patient pursuant to <u>A06-000</u>, <u>Consent to Treatment</u>, shall include language that allows for the possible presence of an industry representative.
 - (b) The industry representative shall read and sign the perioperative services orientation guide and sign-in. The representative shall also provide Purchasing with electronic documentation of annual TB screening, Hepatitis B, MMR, and varicella immunizations.
 - (c) Industry representatives shall wear proper attire in the operating room and other procedure areas, which includes a red bouffant cap.
 - (d) Industry representatives shall remain with the designated patient at all times and shall not visit other physicians within the operating room or procedure area.
 - (e) Industry representatives shall not provide medical or patient care directly or indirectly. They shall not scrub in for the surgical/procedural case and, in general, they shall not open sterile supplies onto the field or touch the patient. Industry representatives in the patient area to program implantable medical devices may open supplies or touch the patient only if necessary to program the implantable device.

Policy # A01-105 Industry Representatives (Code of Conduct Addendum, Part 3 of 5) 3

- (f) Industry representatives shall only be present in the operating room/procedure area during the period of time in which the product is in use.
- (g) Any problems related to industry representatives shall be reported to Purchasing and Operating Room Enterprise Administration.

Violation of Policy

Industry representatives who violate the terms of this or any other UK HealthCare policy shall be issued a first warning. This warning will be sent to the product sales representative's supervisor. A second violation may result in that representative being banned from the hospital. For any known or suspected violations contact the Office of Corporate Compliance.

Gifts, Gratuities, and Entertainment

Gifts, gratuities and entertainment offered by product sales representatives shall be governed by A01-160, Annual Disclosures of Financial Conflicts of Interest.

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

See Also

Additional information, definitions, and authorization procedures are outlined in policies and administrative regulation below:

A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)

A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)

A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum, Part 5 of 5)

AR 3:9, Consulting and Other Overload Employment Outside the University

Persons and Site	s Affected				
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Departments: [UKI	HC Policy Sites	Departments			
Policies Replace	d		=	~	· .
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Effective Date: 2	/24/2020		Review/Revision Dates: 8/12/2015; 2/24/2020		
Approval by and	date:		G.		
Name Rebector Signature Name M. Gwe Signature Name Angela Signature Name Jennifer Name Jay Grid Signature Name John W Signature Name Colleen Signature Name Mark N Signature	and the control of th	nce Officer Nurse Executive ence & Operate nistrative Office sician Executive sident for Amb	ve ions Officer er ve, Interim ulatory Ope tal Operatio	erations ns	Date $\frac{5}{29}/20$ Date $\frac{5}{7}/2020$ Date $\frac{5}{7}/2020$ Date $\frac{5}{7}/2020$ Date $\frac{5}{7}/2020$ Date $\frac{5}{27}/2020$ Date $\frac{5}{27}/2020$ Date $\frac{6}{27}/2020$



Policy # A01-155

Title/Description UK HealthCare Members Interactions with Industry Representatives (Code of Conduct Addendum, Part 4 of 5)

Purpose: To provide guidance for the interaction of UK HealthCare Members with Industry Representatives.

Policy

Procedure

Gifts and Meals

Industry Representative Access to UK Healthcare Members

Ghostwriting and Speakers Bureaus

Participation in and Publication of Industry-Sponsored Research

Consulting Agreements

Training and Site Visits

Continuing Medical Education

Scholarships

Other Related Policies

Ouestions

See Also

Persons and Sites Affected

Policies Replaced

Effective Date

Review/Revision Dates

Policy

The purpose of this policy is to act as an addendum to the <u>University of Kentucky Ethical Principles and Code of Conduct</u>, <u>UK HealthCare Code of Ethics</u> and <u>UK HealthCare Conflicts of Interest Policy #A01-030</u>. The addendum establishes guidelines for interactions with Industry representatives throughout the UK HealthCare System. The policy applies to all UK Healthcare Members. For the purpose of this policy, industry representative means any industry representative, vendor, or supplier which does business or seeks to do business with UK HealthCare, including, but not limited to, a person, individual, proprietorship, firm, partnership, limited partnership, joint venture, joint stocking company, syndicate, business, statutory trust, estate, company, corportation, limited liability company, association, club, committee, organization or group of persons acting in concert that does business or seeks to do business with UK HeathCare. "UK HealthCare Members" is defined as University of Kentucky Trustees, UK

¹ For purposes of this policy, industry representative shall not include any entity with which UK HealthCare is legally required to interact, such as a licensing, regulatory, accrediting or organ procurement organization, provided

HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery and to all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care. Interactions with Industry occur in a variety of on-campus and off-campus circumstances, including marketing of new products, training related to new purchases, research, research support, educational support for trainees and continuing medical education programs. Many aspects of these interactions are very positive and important for promoting the educational, clinical and research missions of UK HealthCare. However, these interactions are ethical and cannot create conflicts of interest, real or perceived, that could endanger patient safety, data integrity, the integrity of our education and training programs or the reputation of our members and our institution.

Procedure

Gifts and Meals

- UK Healthcare Members may not accept gifts from industry representatives, regardless of
 the nature or value. Gifts include anything of value provided at no charge or at a
 discount. For any known or suspected violations contact the Office of Corporate
 Compliance.
- 2. Industry-sponsored meals or snacks are not allowed unless the meal or snack is in conjunction with an accredited continuing education program and the meal or snack is offered to all attendees.
- 3. Philanthropic gifts are accepted through the UK HealthCare Office of Philanthropy.
- 4. Benefits provided by KMSF are not considered gifts and therefore are exempt from this policy.
- 5. UK HealthCare Members may participate in events such as golf scrambles and dinners that take place solely to benefit bona fide not-for-profit organizations, e.g. the American Heart Association, American Cancer Society, Kentucky Children's Hospital.

Industry Representative Access to UK Healthcare Members

- 1. Industry representatives are required to make an appointment in order to meet with a UK HealthCare Member. These appointments are in non-patient, non-care areas.
- 2. Industry representatives may not interact directly with students or house officers unless supervised by a UK HealthCare Faculty.
- 3. At the request of the attending physician, an industry representative may be allowed in a patient care area. The attending physician assumes responsibility for the representative

the purpose of the interaction is to meet those legal requirements. However, if such entity or its affiliates does business or seeks to do business with UK HealthCare and is interacting with UK HealthCare members for such business purposes then this policy applies.

- and shall remain in the treatment area throughout the representatives interaction. The interaction with the patient is guided by UK HealthCare policies governing patient privacy and confidentiality, informed consent and quality patient care.
- 4. More information on Industry Representativ in UK Healthcare facilities can be found in policy <u>UK HealthCare Policy #A01-105</u>.

Ghostwriting and Speakers Bureaus

- 1. "Ghostwriting" refers to an industry marketing scheme in which industry representatives create lectures or academic publications to further their cause and then recruit credentialed professionals to present or publish the information as if it was the credentialed professional's independent work. Ghostwriting is considered academic dishonesty and is not allowed by any UK HealthCare Member.
- 2. UK HealthCare Members may not participate in Speaker's Bureaus or any other speaking arrangement in which the UK HealthCare Member does not have complete control over the content of the presentation.
- 3. Any contract regarding speaking engagements is reviewed by the University of Kentucky Office of Legal Counsel prior to the speaking engagement.

Participation in and Publication of Industry-Sponsored Research

- 1. UK Healthcare Members who participate in any industry sponsored research shall abide by the <u>University of Kentucky Research Conflict of Interest and Financial Disclosure Policy</u> as well as this Code of Conduct Addendum.
- 2. UK Healthcare Members who conduct research sponsored by industry shall have an active role in the research project. This participation includes:
 - (a) Substantial input or full agreement with the trial design
 - (b) The study's steering committee has access to raw data
 - (c) Responsibility for data analyses and interpretation of results.
- 3. UK Healthcare Members shall retain the right to publish the results without consent or prolonged review from industry representatives.
- 4. Prior to publication, the authors shall provide full disclosure of any possible conflicts of interest.

Consulting Agreements

In all consulting agreements, the University of Kentucky Policies <u>AR 3:9 Consulting and Other Overload Employment</u> and <u>Human Resources Policy and Procedure Number 18.0 Outside Employment</u> apply. <u>UK HealthCare Conflicts of Interest Policy #A01-030</u> and college-specific Practice Plans also apply.

1. After receiving advanced approval pursuant to AR 3:9 Faculty Consulting and Other Overload Employment, UK Healthcare Members may work as consultants, providing

- bona fide services for compensation at fair market value. Expenses such as travel, hotel and meals associated with providing the bona fide services may be reimbursed.
- 2. For UK HealthCare Members affiliated with one of the UK HealthCare Colleges, the approval process in AR 3:9 Consulting and Other Overload Employment Section B shall be followed. This process requires that consulting activities be approved by the college dean prior to agreeing to or beginning any work.
- 3. All consulting work requires a contract with the outside agency. The contract includes clear deliverables such as a description of services provided, compensation and length of service. The contract is approved by the University of Kentucky's Office of Legal Counsel prior to the agreement to start any work.
- 4. Benefits from consulting agreements are fully disclosed on the applicable financial conflict of interest forms within 30 days of receipt of benefits.
- 5. Consulting income for UK HealthCare clinical faculty with a M.D. or D.O. degree that are members of College of Medicine Practice Plan that constitutes "clinical income" as defined by (1) the Practice Agreement and Assignment signed by the faculty member; (2) AR 3:14; and (3) the College of Medicine Practice Plan Addendum shall be paid to the Plan and not the faculty member. An exception to this requirement may be granted by the Dean of the College of Medicine pursuant to AR 3:14 XII.A. Requests for such an exception shall be made in writing through the respective director or chair to the Dean.

Training and Site Visits

- 1. UK HealthCare Members may be required to travel to other locations in order to train for or view new equipment or systems. Such travel is only considered legitimate if the product, equipment or training cannot reasonably be brought to the University campus.
- 2. All site visits must comply with the Commonwealth of Kentucky Model Procurement Code and UK Purchasing rules, and are arranged in coordination with the UK Purchasing Division.
- 3. 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.
- 4. If the University has a purchasing agreement that includes travel to a site for review or training, then 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 are reasonable.

Continuing Medical Education

- 1. University of Kentucky/UK HealthCare-hosted and properly accredited (CE Central, ACCME or other) continuing education events may be funded in part by industry. Payment are made to a college, department, center or division but not an individual. Funding sources are disclosed to the accrediting agency.
- 2. Industry representatives shall not be allowed to select a topic or speaker for any University of Kentucky/UK HealthCare-hosted continuing education events.

Policy # A01-155 UK HealthCare Members Interactions with Industry Representatives (Code of Conduct Addendum, Part 4 of 5) 4

- 3. Industry-sponsored meals and snacks offered as part of an accredited continuing education event are allowed given the meal or snack is available to all participants and of reasonable expense.
- 4. Industry-initiated continuing education events or professional educational activities may not be held on campus.
- 5. Industry may not directly or indirectly subsidize an individual UK Healthcare Member's attendance at any conference or meeting. Industry may donate funds to a conference planning organization that in turn may reduce the conference fees for all attendees.
- 6. UK Healthcare Members attending off campus vendor-initiated and non-accredited meetings typically called "professional educational experiences" may not accept gifts or meals unless they reimburse the sponsor of the event for the costs of the gift or meal.

Scholarships

- 1. Industry representatives may provide support in the form of scholarships for students and house officer's attendance at accredited educational conferences. The scholarship funds are approved by the Dean of the respective college and are set up as a gift through the UK HealthCare Office of Development.
- Selection of recipients for industry sponsored scholarships shall be completed through the Dean's office of the appropriate college. The Dean may delegate the selection to others in the college. Industry representatives may not be involved in the selection process.
 Written documentation of the selection process is required.
- 3. The recipient is not subject to any expectation of providing something in return for receiving the support, i.e. "quid pro quo".
- 4. The policy does not apply to regional or national merit based awards or to formal research grants supported by industry.

Other Related Policies

- 1. Samples The expectations for handling pharmaceutical samples are outlined in Pharmacy Policy PH14.06.045 Pharmaceutical Samples
- 2. Pharmacy and Therapeutics Committees Pharmaceutical and Medical Device Procurement is governed by Section B-2 of the University of Kentucky Business Operations Manual and by UK HealthCare Policy #A01-140.
- 3. Industry Representatives The policy regarding industry representatives and their interactions with UK HealthCare Members is outlined in UK HealthCare Policy #A01-105.
- Annual Disclosure of Financial Conflicts of Interest The expectations for faculty and select staff in regards to disclosing financial conflicts of interest can be found in UK HealthCare Policy #A01-160

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

See Also

Additional information, definitions, and authorization procedures are outlined in policies and administrative regulation below:

A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)

A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)

A01-105, Industry Representatives (Code of Conduct Addendum, Part 5 of 5)

AR 3:9, Consulting and Other Overload Employment Outside the University

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Policy # A01-160

Title/Description Annual Disclosure of Financial Conflicts of Interest (Code of Conduct Addendum, Part 5 of 5)

Purpose: To outline the procedure for full disclosure of financial conflicts of interest by UK HealthCare members.

Policy
Procedure
Annual Reporting
Questions
See Also
Persons and Sites Affected
Policies Replaced
Effective Date
Review/Revision Dates

Policy

The University of Kentucky along with UK HealthCare has an obligation to the public to conduct its activities transparently and with integrity. Both entities are committed to avoiding financial conflicts of interest that may compromise or appear to compromise the integrity and objectivity of patient care, research, and the safety of human research subjects. Because the University encourages its members to engage in outside activities and relationships that enhance its missions, real or perceived conflicts of interest may arise. Full disclosure of any possible conflicts is the key to identifying and managing financial conflicts. The policy applies to all UK Healthcare Members. For the purpose of this policy "UK HealthCare Members" is defined as University of Kentucky Trustees, UK HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery, and all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those faculty members engage in clinical care.

Procedure

Annual Reporting

UK HealthCare faculty and designated staff must complete annual financial disclosures.

- 1. All UK HealthCare faculty and staff as identified by the Conflict Committee must complete a disclosure specific to UK HealthCare. This disclosure is completed annually or as requested and includes:
 - (a) All outside employment and consulting agreements
 - (b) All professional income from sources other than the University
 - (c) Relationships with vendors, including but not limited to research support, vendor boards, and advisory boards
 - (d) Participation in vendor sponsored or supported educational or informational programs
 - (e) All other relationships with vendors, including but not limited to vendor sponsored or reimbursed travel.
 - (f) Annual disclosures are made through the UK HealthCare Corporate Compliance Office. Information reported will be treated as personal information contained in the faculty Standard Personnel File or the staff human resources file, to the extent permitted by law. Compliance with this policy shall be considered an official University need for access to reported information by department heads and other University officials, and is shared in coordination with other administrative areas that collect conflict of interest information.
- 2. For UK HealthCare members who accept extramural funding of any kind, the University disclosure is required as outlined in <u>University of Kentucky Policy AR 7:2 Financial Conflict of Interest in Research</u>. Disclosures include:
 - (a) Ownership of any publicly or non-public traded entities
 - (b) Income from intellectual property
 - (c) Research conducted on human subjects
 - (d) Research funded by PHS
- 3. Changes to financial disclosures must be updated within 30 days of the change.
- 4. If a financial conflict is reported at either disclosure point, a management plan will be requested by an institutional official.
- 5. The Management Plan will be reviewed by the Research Conflict of Interest Committee (RCOIC) or by the UK HealthCare Conflict Committee, or both. After reviewing the management plan, the committees have several options:
 - (a) Accept the management plan as submitted
 - (b) Amend the plan to decrease the chance for conflict
 - (c) Require changes to eliminate the conflict. Examples of required changes include but are not limited to:

Policy # A01-160 Annual Disclosure of Financial Conflicts of Interest (Code of Conduct Addendum, Part 5 of 5)

- i. Removal from participation in the research project
- ii. Divestiture of the financial interest
- iii. Termination of relationship that creates the conflict

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

See Also

Additional information, definitions, and authorization procedures are outlined in policies and administrative regulation below:

A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)

A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)

A01-105, Industry Representatives (Code of Conduct Addendum, Part 3 of 5)

A01-155, Interaction with Industry Representatives (Code of Conduct Addendum, Part 4 of 5)

AR 3:9, Consulting and Other Overload Employment Outside the University

Page 3 Effective Date: 2/24/2020

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