PR 6

Office of the President June 16, 2023

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 updates have occurred to all five policies: (i) the policies have been placed on the most recent UK HealthCare policy template that was adopted in October 2021 based on The Joint Commission recommendations; (ii) a scope statement has been added, as required by the new policy template; and (iii) references to other policies (including UK AR 3:9 and UK GR XIV) have been added and/or updated.

Additionally, recent edits were made to the following individual policies. For the *Conflicts of Interest* policy, the statements related to gifts and loans from patients were revised to clarify that these acts are unauthorized (except for small tokens of gratitude), and statements related to contracted services and disclosures were modified to add clarity. For the *Industry Representatives* and *UK HealthCare Members Interactions with Industry Representatives* policies, the definition of "industry representatives" was revised to include manufacturers and group purchasing organizations per regulatory requirements (42 CFR § 403.902), and the policies were revised and renamed to also include "service providers."

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

EXECUTIVE SUMMARY—CODE OF CONDUCT POLICIES May 30, 2023

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.
- The policies were put on the most recent UK HealthCare policy template (that was adopted in October 2021 based on The Joint Commission recommendations).
- A scope statement was added to each policy (stating the policy applies to all UK HealthCare members), as required by the new policy template.
- References to other policies (including UK AR 3:9 and UK GR XIV) were added and/or updated.

SUMMARY OF SPECIFIC CHANGES TO INDIVIDUAL POLICIES:

- A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
 - a. No significant content changes other than general changes mentioned above.
- A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
 - a. The word "unauthorized" was removed from the below statements related to loans and gifts from patients: *Without prior authorization, no UK HealthCare Member shall…*

Accept an unauthorized loan from a patient for whom they have provided care, services, and/or referred services.

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.

- Regarding contracted services, the following revisions were made (additions are underlined): UK HealthCare Members and their immediate families shall not... Perform <u>contracted</u> services for UK HealthCare where the UK HealthCare member would have is in a position of influence.
- Regarding disclosures, the following revisions were made (additions are underlined): All UK HealthCare Members shall follow these guidelines: They shall <u>disclose</u> 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, <u>and may not pursue any such activity until it has been authorized.</u>
- A01-105, Industry Representatives and Service Providers (Code of Conduct Addendum, Part 3 of 5) and A01-155, UK HealthCare Members Interactions with Industry Representatives and Service Providers (Code of Conduct Addendum Part 4 of 5)
 - a. The definition of "industry representatives" was revised as set forth below in alignment with 42 CFR § 403.902, and "service providers" was also included in the policies and policy titles:

Industry Representatives and Service Providers

For the purpose of this policy, "industry representatives and service providers" means any "manufacturer(s)" or "group purchasing organization(s)" as those terms are defined below. It also includes other outside entities and individuals who provide services (for example, IT services) to UK HealthCare. Manufacturer

A "manufacturer" is an outside entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or any entity under common ownership with a manufacturer. 42 CFR § 403.902.

Group Purchasing Organization

A "group purchasing organization" means an entity that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of other individuals or entities. 42 CFR § 403.902.

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

a. No significant content changes other than general changes mentioned above.



TITLE Code of Ethics (Code of Conduct Addendum, Part 1 of 5)			IDENTIFICATION NUMBER A01-005
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky	X Enterprise	X Enterprise	CHANDLER HP01-02
/ UK HealthCare	□ Chandler	□ Nursing	
	🗆 Good Samaritan	□ Department	
	🗆 КСН	□ Guideline	
	Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE:	
Review Dates: 10/2011; 10/7/2015;			
10/1/2018; 02/24/2020 <u>; 3/6/2023</u>			

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.

PURPOSE

The purpose of this policy is to set forth the code of ethics applicable to the operations of UK HealthCare.

SCOPE

The policy applies to all UK Healthcare Members.

DEFINITIONS

UK HealthCare Members

<u>"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 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 individuals engage in clinical care.</u>

Consistent with the mission and vision of UK HealthCare, Living DIReCT¹, and the , 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.

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

- 6. Responsible resource management.
- 7. Teamwork, cooperation, and flexibility.
- 8. Differences among people.

PROCEDURES

UK HealthCare Values

<u>Consistent with the mission and vision of UK HealthCare, Living DIReCT², and the Behavioral Standards, UK HealthCare values:</u>

- <u>1. Integrity, honesty, fairness, and ethical behavior in all that we do.</u>
- 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.

Patient Care

Patients are admitted, treated, discharged, or transferred based on their clinical needs and without regard to age, race, ethnicity, culture, color, national origin, creed, language, sex, gender identity or expression, sexual orientation, appearance, socio economic status, physical or mental disability, diagnosis, religion, military, or veteran status, uniformed service, or political belief. 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.

² Living DIReCT values: Diversity, Innovation, Respect, Compassion, and Teamwork. See more at: https://www.uky.edu/pe/uk-healthcare-values

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.

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 ResponsibilitiesA08-105</u> (Patient Rights and Responsibilities). 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, Conflicts of InterestA01-030 (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.

REFERENCES

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

- 1. A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
- 2. <u>A01-105, Industry Representatives and Service Providers (Code of Conduct Addendum, Part</u> <u>3 of 5)</u>
- 3. <u>A01-155, UK HealthCare Members Interactions with Industry Representatives and Service</u> <u>Providers (Code of Conduct Addendum, Part 4 of 5)</u>
- 4. A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum, Part 5 of 5)
- 4.5. A08-105 (Patient Rights and Responsibilities)
- 5.<u>6.AR 3:9, Consulting and Other Overload Employment Outside the UniversityAR 3:9 (Faculty</u> Consulting and Other Overload Employment)

Approval	
NAME AND CREDENTIALS:	NAME AND CREDENTIALS:
Noelle True	Brett Short
TITLE:	TITLE:
Assistant Chief Compliance Officer	Chief Compliance Officer
SIGNATURE	DATE
SIGNATURE	DATE
Signature	Дате



TITLE Industry Representatives (Code of Conduct Addendum, Part 3 of 5)Industry Representatives and Service Providers (Code of Conduct Addendum, Part 3 of 5)			IDENTIFICATION NUMBER A01-105
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky	X Enterprise	X Enterprise	
/ UK HealthCare	Chandler	□ Nursing	
	Good Samaritan	Department	
	🗆 КСН	Guideline	
	□ Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE: 4/9/2022	
Review Dates: 10/21/2019; 02/24/2020, 4/8/2022 <u>; 3/6/2023</u>			

Interactions with <u>i</u>Industry <u>and service providers</u> 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.

PURPOSE

The purpose of this policy is to act as guidance for industry representatives <u>and service providers</u> in their interactions with UK HealthCare Members. It also sets expectations for behavior when <u>an industry</u> representative or service provider is on the premises of any UK HealthCare facility.

SCOPE

Thise policy applies to all industry representatives <u>and service providers</u> in their interactions with UK HealthCare <u>M</u>members.

DEFINITIONS

UK HealthCare Members

"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 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 individuals engage in clinical care.

Industry Representatives and Service Providers

[±] 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.

For the purpose of this policy, "industry representatives and service providers" means any "manufacturer(s)" or "group purchasing organization(s)" as those terms are defined below. It also includes other outside entities and individuals who provide services (for example, IT services) to UK HealthCare.

Manufacturer

A "manufacturer" is an outside entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or any entity under common ownership with a manufacturer. $\underline{42 \text{ CFR } \S 403.902}$.

Group Purchasing Organization

A "group purchasing organization" means an entity that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of other individuals or entities. <u>42 CFR § 403.902</u>.

PROCEDURES

Training, Orientation and Other Requirements for Industry Representatives

Before their first visit or appointment, all pharmaceutical industry representatives must register with UK HealthCare Pharmacy Services Administration. All other industry representatives <u>and service</u> <u>providers</u> must register with UK HealthCare Purchasing. When registering, the industry representative <u>or service provider</u> 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 <u>or service provider</u> shall adhere to <u>Behavioral Standards</u>, as well as to American Medical Association and Research & Manufacturers of America guidelines. Documentation of completed training will be electronically maintained with Pharmacy or with Purchasing, as appropriate. The <u>industry</u> representative <u>or service provider</u> shall also provide Purchasing or Pharmacy with electronic documentation of annual TB screening, Hepatitis B, MMR, and varicella immunizations.

Clinical contractors shall also follow all UK HealthCare's policies to ensure compliance with all regulatory requirements and contractual obligations. In addition to the requirements listed above, industry representatives and clinical contractors are required to abide by <u>Policy A03-125 (COVID 19)</u>.

Registration of Visits

Industry representatives <u>and service providers</u> 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 <u>and service providers</u> shall be issued an identification badge for appropriate access. The badge shall include the individual's 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 and Service Provider Access to UK Healthcare Members

- 1. Industry representatives <u>and service providers</u> are required to make an appointment in order to meet with a UKHealthCare Member. These appointments must be in non-patient, non-care areas <u>(unless as set forth below)</u> and shall be between the hours of 6:00 am and 5:00 pm, Monday through Friday.
- 2. Industry representatives <u>and service providers</u> may not interact directly with students or house officers unless <u>supervised</u> by a UK HealthCare Member.

Gifts and Meals

- 1. UK Healthcare Members may not accept gifts from industry representatives or service providers 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 <u>A14-135, Medication Sample</u> <u>Management</u>.
- 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. <u>See A07-115 (Value Analysis Process)</u>.

Industry Representatives and Service Providers in Patient Care Areas

- 1. At the request of the attending physician, an industry_representative or service provider 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 <u>or service provider</u> may be allowed in an operatingroom or other procedure areas to provide technical support.
 - a) The special consent signed by the patient pursuant to <u>A06-000, Consent to Treatment</u>, shall include language that allows for the possible presence of an industry representative <u>or service provider</u>.
 - b) The industry representative <u>or service provider</u> shall read and sign the perioperative services orientationguide and sign-in.
 - c) Industry representatives <u>and service providers</u> shall wear proper attire in the operating room and otherprocedure areas, which includes a red bouffant cap.
 - d) Industry_-representatives <u>and service providers</u> 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 and service providers 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/service providers in the patient area to program implantable —medical devices may open supplies or touch the patient only if necessary to program the implantable device.

- f) Industry representatives <u>and service providers</u> 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 <u>or service providers</u> shall be reported to Purchasing <u>and and</u>Operating Room Enterprise Administration.

Violation of Policy

Industry representatives <u>and service providers</u> 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 <u>A01-160, Annual Disclosures of Financial Conflicts of InterestA01-155 (UK HealthCare Members</u> Interactions with Industry Representatives).

Questions

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

REFERENCES

- 1. A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
- 2. A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
- 3. A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum,Part 5 of 5)
- 4. AR 3:9, Consulting and Other Overload Employment Outside the University
- 5. A03-125, COVID-19
- 6. 42 CFR § 403.902

APPROVAL

NAME AND CREDENTIALS:	NAME AND CREDENTIALS:	
Noelle True	Brett Short	
TITLE:	TITLE:	
Assistant Chief Compliance Officer	Chief Compliance Officer	
SIGNATURE		Date [MM/DD/YYYY]
SIGNATURE		Date [MM/DD/YYYY]

REFERENCES

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)
- 1. A01 030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
- 2. <u>A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum,</u> <u>Part 5 of 5)</u>
- 3. AR 3:9, Consulting and Other Overload Employment Outside the University
- <u>A03-125 COVID-19</u>

APPROVAL

Name and Credentials:	Name and Credentials:	
Noelle True	Brett Short	
TITLE:	TITLE:	
Senior Compliance Manager	Chief Compliance Office	F
SIGNATURE		Date [MM/DD/YYY]
Signature		Date [MM/DD/YYY]



TITLE Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)			IDENTIFICATION NUMBER A01-030
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky	X Enterprise	X Enterprise	CHANDLER HP01-03
/ UK HealthCare	□ Chandler	□ Nursing	
	🗆 Good Samaritan	□ Department	
	🗆 КСН	Guideline	
	Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE:	
Review Dates: 8/12/2015; 10/1/2018; 02/24/2020 <u>: 3/6/2023</u>			

UK HealthCare prohibits participation in any activity that may conflict with the purpose or objectives of the UK HealthCare Enterprise.

PURPOSE

The purpose of this policy is to provide guidance for UK HealthCare <u>M</u>members regarding participation in activities that may be in conflict with the purpose or objectives of the UK HealthCare enterprise.

SCOPE

The policy applies to all UK Healthcare Members.

DEFINITIONS

UK HealthCare Members

<u>"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 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 individuals engage in clinical care.</u>

PROCEDURES

- 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 <u>"for profit"</u> enterprise that does business with UK HealthCare.
 - c) Accept an unauthorized gift, Ioan, food, or other favor from an outside agent that does, or seeks to do, business with UK HealthCare. See<u>policy A01-160, Annual</u> <u>Disclosure of Financial Conflicts of Interest.A01-160 (Annual Disclosure of Financial Conflicts of Interest).</u>
 - d) Accept an <u>unauthorized</u>-loan from a patient for whom they have provided care, services, and/or referred services.

- e) Accept an <u>unauthorized</u> 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.
- f) Disclose or otherwise use confidential UK HealthCare information outside of official job requirements.
- g) Compete with UK HealthCare, either directly or indirectly, in the purchase or sale of property or property rights.
- h) Represent another health care institution in any transaction where they or a relative have a substantial interest.
- i) 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 <u>an</u> authorized designee.
- 2. UK HealthCare Members and their immediate families shall not:
 - a) Perform <u>contracted</u> services for UK HealthCare where the UK HealthCare member would have is in 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 <u>disclose not have</u> any interest or relationship that <u>is prohibited</u>, or might cause a conflict of interest, or give the appearance of a conflict of interest, <u>and may</u> <u>not pursue any such activity until it has been authorized</u>.
 - b) They shall contact the <u>compliance officerOffice of Corporate Compliance</u> 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 on-line report form 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.

References

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

- 1. <u>A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)</u>
- 2. <u>A01-105, Industry Representatives and Service Providers (Code of Conduct Addendum, Part</u> <u>3 of 5)</u>

- 3. <u>A01-155, UK HealthCare Members Interactions with Industry Representatives and Service</u> <u>Providers (Code of Conduct Addendum, Part 4 of 5)</u>
- 4. <u>A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum,</u> <u>Part 5 of 5)</u>
- 5. <u>AR 3:9, Consulting and Other Overload Employment Outside the UniversityAR 3:9 (Faculty</u> <u>Consulting and Other Overload Employment)</u>

Approval

NAME AND CREDENTIALS:	NAME AND CREDENTIALS:	
Noelle True	Brett Short	
TITLE:	Тітіе:	
Assistant Chief Compliance Officer	Chief Compliance Officer	
SIGNATURE	DATE	
SIGNATURE	Дате	



TITLE UK HealthCare Members Interactions with Industry Representatives (Code of Conduct Addendum, Part 4 of 5)UK HealthCare Members Interactions with Industry Representatives and Service Providers (Code of Conduct Addendum, Part 4 of 5)			IDENTIFICATION NUMBER A01-155
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky	X Enterprise	X Enterprise	
/ UK HealthCare	Chandler	□ Nursing	
	Good Samaritan Department		
	□ Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE:	·
Review Dates: 8/12/2015; 10/21/2019; 2/24/2020 <u>; 3/6/2023</u>			

UK HealthCare Member interactions with industry and service providers occur in a variety of oncampus 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 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. The purpose of this policy is to act as an addendum to the University of Kentucky Ethical Principles and Code of Conduct, and UK HealthCare Conflicts of Interest Policy #A01-030. The addendum establishes guidelines for interactions with Industry representatives throughout the UK HealthCare System.

PURPOSE

This policy is an addendum to UK GR XIV (Ethical Principles and Code of Conduct), A01-005 (Code of Ethics) and A01-030 (Conflicts of Interest). Its The-purpose of this policy is to provide guidance for the interaction of UK HealthCare Members with Industry industry representatives Representatives and service providers.

SCOPE

This policy applies to all UK Healthcare Members, as defined below.

DEFINITIONS

UK HealthCare Members

<u>"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 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 individuals engage in clinical care.</u>

Industry Representatives and Service Providers

For the purpose of this policy, "industry representatives and service providers" means any "manufacturer(s)" or "group purchasing organization(s)" as those terms are defined below. It also includes other outside entities and individuals who provide services (for example, IT services) to UK HealthCare.

<u>Manufacturer</u>

<u>A "manufacturer" is an outside entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or any entity under common ownership with a manufacturer. 42 CFR § 403.902.</u>

Group Purchasing Organization

<u>A "group purchasing organization" means an entity that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of other individuals or entities.</u> 42 CFR § 403.902.

PROCEDURES

Gifts and Meals

- UK Health<u>Ceare Members may not accept gifts from an industry representative or service provider</u>, 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.
- <u>Industry sponsored meals Meals</u> or snacks <u>sponsored by industry or service providers</u> 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.
- 2.3.All other gifts to UK HealthCare Members must be in compliance with UK GR XIV, Section 18 (Acceptance of Gifts and Benefits).
- 3.4. Philanthropic gifts are accepted through the UK HealthCare Office of Philanthropy.
- 4.5. Benefits provided by KMSF are not considered gifts and therefore are exempt from this policy.
- <u>5.6.</u>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 HealthCeare Members

- 1. Industry representatives <u>and service providers</u> 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 <u>and service providers</u> may not interact directly with students or house officers unless supervised by <u>a-</u>UK HealthCare Faculty.
- 3. At the request of the attending physician, an industry representative <u>or service provider</u> may be allowed in a patient care area. The attending physician assumes responsibility for the representative and shall remain in the treatment area throughout the representative's

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 <u>i</u>Industry <u>r</u>Representatives <u>and service providers</u> in UK HealthCeare facilities can be found in <u>A01-105 (Industry Representatives and Service Providers)</u>policy <u>UK</u> <u>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

- UK Health<u>C</u>eare Members who participate in any industry_sponsored research shall abide by <u>UK AR 7:2 (Financial Conflicts of Interest in Research)</u> the <u>University of Kentucky Research</u> <u>Conflict of Interest and Financial Disclosure Policy</u> as well as this <u>Code of Conduct</u> <u>Addendumpolicy</u>.
- 2. UK Health<u>C</u>eare 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: and
 - c) Responsibility for data analyses and interpretation of results.
- 3. UK Health<u>C</u>eare 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</u> <u>Overload Employment AR 3:9 (Consulting and Other Overload Employment), HR Policy and Procedure</u> #18 (Outside Employment), <u>apply. A01-030 (Conflicts of Interest)UK HealthCare Conflicts of Interest</u> <u>Policy #A01-030</u> and college-specific Practice Plans also apply.

- 1. After receiving advanced approval pursuant to <u>AR 3:9</u>, UK Health<u>C</u>eare 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.
- For UK HealthCare Members affiliated with one of the UK <u>Health Professions</u> <u>HealthCare</u> Colleges, the approval process in <u>Section B of AR 3:9 Consulting and Other Overload</u> <u>Employment Section BAR 3:9</u> -shall be followed. This process requires that consulting activities be approved by the <u>college deanProvost</u> prior to agreeing to or beginning any work.

- 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 <u>may need is approvaled</u> 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); 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 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 <u>Commonwealth of Kentucky Model Procurement Code</u>, <u>KRS Chapter 45A</u> 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

- University of Kentucky/UK HealthCare-hosted and properly accredited (CE Central, ACCME or other) continuing education events may be funded in part by industry. <u>If industry support is</u> provided, it must be <u>Payment are</u> made to a college, department, center or division but <u>not</u> <u>directly not-to</u> an individual. Funding sources are disclosed to the accrediting agency.
- 2. Industry representatives and service providers shall not be allowed to select a topic or speaker for any University of Kentucky/UK HealthCare-hosted continuing education events.
- 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 <u>campusUK HealthCare property</u>.
- 5. Industry may not directly or indirectly subsidize an individual UK Health<u>C</u>eare 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.
- UK Health<u>C</u>eare 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.<u>UK</u>

HealthCare members can, however, attend such meetings as long as no gifts or meals are accepted.

Scholarships

- Industry representatives and service providers 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.
- 2. 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. A14-135 (Medication Sample Management)
- <u>A07-115 (Value Analysis Process)</u><u>Pharmacy and Therapeutics Committees</u> <u>Pharmaceutical</u> and <u>Medical Device Procurement is governed by Section B-2 of the University of Kentucky</u> <u>Business Operations Manual</u> and by UK HealthCare Policy <u>#A01-140</u>.
- 3. <u>Industry Representatives The policy regarding industry representatives and their</u> <u>interactions with UK HealthCare Members is outlined in UK HealthCare Policy #A01-105.</u>
- 4. <u>Annual Disclosure of Financial Conflicts of Interest The expectations for faculty and select</u> <u>staff in regards to disclosing financial conflicts of interest can be found in UK HealthCare</u> Policy #A01_160

Questions

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

REFERENCES

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

- 1. UK GR XIV (Ethical Principles and Code of Conduct)
- 1.2. A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
- 3. A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
- 4. A01-105, Industry Representatives and Service Providers (Code of Conduct Addendum, Part 3 of 5)
- 2.5.A01-160, Annual Disclosure of Financial Conflicts of Interest (Code of Conduct Addendum, Part 5 of 5)
- 3.<u>6.A01-105, Industry Representatives (Code of Conduct Addendum, Part 5 of 5)</u>HR Policy and Procedure #18 (Outside Employment)
- 7. AR 3:9 (Faculty Consulting and Other Overload Employment-Outside the University)
- 8. AR 3:14 (Practice Plans for Health Science Colleges and University Health Services)

- 9. UK AR 7:2 (Financial Conflicts of Interest in Research)
- 10. A14-135 (Medication Sample Management)
- 11. A07-115 (Value Analysis Process)

4<u>.12. 42 CFR § 403.902</u>

NAME AND CREDENTIALS:
Brett Short
TITLE:
Chief Compliance Officer
DATE
DATE



TITLE Annual Disclosure of Financial Conflicts of Interest (Code of Conduct Addendum, Part 5 of 5)			IDENTIFICATION NUMBER A01-160
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky	X Enterprise	X Enterprise	
/ UK HealthCare	Chandler	□ Nursing	
	🗆 Good Samaritan	□ Department	
	🗆 КСН	Guideline	
	□ Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE:	
Review Dates: 8/12/2015; 10/1/2018; 10/21/2019; 2/24/2020 <u>; 3/6/2023</u>			

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.

PURPOSE

The purpose of this policy is to outline the procedure for full disclosure of financial conflicts of interest by UK HealthCare \underline{M} members.

SCOPE

The policy applies to all UK Healthcare Members.

DEFINITIONS

UK HealthCare Members

<u>"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 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 individuals engage in clinical care.</u>

PROCEDURES

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 1:
- 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; and
- e) All other relationships with vendors, including but not limited to vendor sponsored or reimbursed travel...

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 <u>Mmembers</u> who accept extramural funding of any kind, the <u>Universitya</u> <u>financial interests</u> disclosure is required as outlined in <u>University of Kentucky Policy AR 7:2</u> <u>Financial Conflict of Interest in ResearchUK AR 7:2</u> (Financial Conflicts of Interest in Research). Disclosures include:
- 3. Ownership of any publicly or non-public traded entities
- 4. Income from intellectual property
- 5. Research conducted on human subjects
- 6.2. Research funded by PHS
- 7.<u>3.</u>Changes to financial disclosures must be updated within 30 days of the change.
- 8.4. If a financial conflict is reported at either disclosure point<u>determined</u>, a management plan will be requested by an institutional official.
- 9.5. The Management Plan will be reviewed by the Research Conflict of Interest Committee (RCOIC) or by the UK HealthCare Conflict <u>of Interest</u> 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:
 - (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.

REFERENCES

¹ Exclusions include income from the Lexington VA, and income associated with participation in an NIH study section. See AR 3:9 (Consulting and Other Overload Employment Outside the University): UK AR 7:2 (Financial Conflicts of Interest in Research).

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

- 1. A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
- 2. <u>A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)</u>
- 3. <u>A01-105, Industry Representatives and Service Providers (Code of Conduct Addendum, Part</u> <u>3 of 5)</u>
- 4. <u>A01-155, UK HealthCare Members Interactions with Industry Representatives and Service</u> <u>Providers 7(Code of Conduct Addendum, Part 4 of 5)</u>

5. AR 3:9 (-Consulting and Other Overload Employment Outside the University)

5.6.UK AR 7:2 (Financial Conflicts of Interest in Research)

Approval

NAME AND CREDENTIALS:	NAME AND CREDENTIALS:	
Noelle True	Brett Short	
TITLE:	TITLE:	
Assistant Chief Compliance Officer	Chief Compliance Officer	<u>_</u>
SIGNATURE		DATE
SIGNATURE		DATE