Introduction

The creation, organization, powers and responsibilities are described and governed by state law in Title 21 of the Indiana Code. Pursuant to that legislation, the governing body is the “Trustees of Indiana University.” Governance of Indiana University is vested in a board of nine Trustees, as provided in the Indiana Code. Three are elected by the alumni of Indiana University, one trustee each year, to serve three-year terms and the remaining six trustees (one of whom shall be a student) are appointed by the governor of the state of Indiana. A set of Bylaws have been created by the Trustees detailing certain organizational rules by which they agree to operate (Attachment A).

The Indiana University School of Medicine (IUSM) is an academic unit of Indiana University. Pursuant to legislation, IUSM operates campuses in nine locations throughout the state of Indiana. Accordingly, IUSM’s mission statement, code of conduct and all other policies (unless otherwise specified), including this policy, apply to all nine campus locations.

IUSM’s Mission, Vision and Values
It is the Mission of the IUSM to advance health in the State of Indiana and beyond by promoting innovation and excellence in education, research and patient care. The IUSM’s Vision is to lead the transformation of health care through quality, innovation and education, and make Indiana one of the nation’s healthiest states. The IUSM’s Core Values are Excellence, reflected in the innovative conduct and advancement of education, research and patient care; Respect for individuals who are affiliated with, or come into contact with IUSM students, residents, fellows, faculty, staff, partners, communities, patients and families; Integrity reflected in actions that appreciate all individuals; Diversity reflected in actions that appreciate all individuals; and Cooperation manifested by collegial communications and collaboration.

Reason for Policy

This Policy provides cohesive guidance for the disclosure, detection, review and management of conflict of interest issues. It shall apply to all nine campuses of the IUSM.

All nine campuses of the IUSM and the entire IU community, including the Trustees of Indiana University, must adhere to the standards of conduct contained in Principles of Ethical Conduct (Attachment B). This policy, adopted by the IU Trustees on December 5, 2013, requires IU “Community Members,” defined as including the Trustees of Indiana University, any employee of Indiana University (including administrators, faculty, staff, temporary and student employees), anyone using university resources and volunteers when speaking on behalf of the university to, among other things, promote a culture of compliance, disclose potential conflicts of interest and adhere to any requirements to manage or eliminate conflicts of interest and ensure that personal relationships do not interfere with objective judgments affecting employment or academic decision-making such as academic progress, grading or admissions decisions.

All nine campuses of the IUSM community are also subject to conflict of interest rules that govern a range of pecuniary and non-pecuniary relationships, issues and transactions. These consist of conflicts of interest that must be disclosed and managed in connection with faculty outside activities (ACA-29)(Attachment C); conflict of interest and conflict of commitment issues involving staff employees of the IUSM (HR-07-40 and HR-07-30) (Attachments D & E); purchasing, or procurement-related conflicts of interest that apply to all employees as well as the Trustees of Indiana University as set forth in the criminal code (Indiana Code 35-44.1-1-4)(Attachment F) and restated by Indiana University policy (FIN-PUR 3.3)(Attachment G); employment situations that constitute nepotism (UA-10)(Attachment H); the Indiana University Code of Academic Ethics (ACA-33)(Attachment I), and activities conducted on behalf of the school by Admissions Committee (Attachment M) and Student Promotions Committee members (Attachment N).

The trustees, administration, faculty, and staff of Indiana University all bear the responsibility of serving the research mission of the University. That mission is
enhanced by the sustained, active interaction of members of the University community with business, government, not-for-profit groups, professional societies, academic institutions, and other individuals and organizations. Moreover, the University recognizes that the members of the University community participate actively in community, political, religious, and cultural activities and institutions, and other personal and economic endeavors.

These many interactions inherently create the potential for conflicts of interest in which University employees’ external activities, income or other interests affect—or reasonably would appear to affect—the manner or extent to which those individuals pursue research within the University. Such real or apparent conflicts, when not appropriately disclosed and addressed, can undermine public and professional confidence in the integrity of University research and sponsored programs. The existence of a real or apparent conflict of interest does not necessarily mean that the outside activity at issue must be avoided or discontinued. Often, conflicts of interest can be dealt with effectively through disclosure or other steps to resolve or manage the conflict (ACA-74)(Attachment J).

The Indiana University School of Medicine also promotes excellence in physician professional development and effectively translates leading-edge research into medical practice through its continuing medical education program. In partnership with physician learners, Indiana University faculty, professional organizations and commercial partners, the Division of Continuing Medical Education develops CME programs in a variety of formats to enable physicians to maintain and enhance their care and to improve patient outcomes through better patient care and disease prevention. The purpose of the Indiana University School of Medicine's Division of Continuing Medical Education (IUSM CME) is to provide lifelong learning opportunities designed to increase knowledge and competence and, to the fullest extent possible, to enhance the ability of physicians and other health care professionals to improve their performance and/or to improve patient and systems-level outcomes.

CME activities employ evidence-based adult learning principles that recognize different learning preferences and styles and target expected outcomes. Types of activities include live learning opportunities such as symposia, conferences, workshops, seminars, live webcasts, mini-fellowships and regularly scheduled sessions; enduring materials in print, multimedia, and Internet-based formats; tools for self-directed learning such as point-of-care (PoC) and performance improvement (PI) opportunities; and other teaching improvement and collaborative projects that utilize CME as part of multi-component strategies to improve population health status and outcomes. When possible, learning formats are highly interactive, include multiple exposures to the same content, and are sequenced for learning. The IUSM CME has an established policy titled “Resolution of Conflict of Interest (COI)” that addresses the process and mechanisms for the identification and resolution of COI in connection with CME activities (Attachment K).

The IUSM is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. IUSM strictly adheres to the ACCME Essential Areas and their Elements as its planning framework. All CME-certified programs are carefully planned so as to comply with these requirements. The IUSM CME is accredited through November, 2017.
Finally, the operation of an academic medical center requires successful relationships with private industry, federal and state governments, philanthropic organizations, and non-governmental organizations. Hence, the IUSM has established an Industry Relations COI policy around interactions with Industry representatives. Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and hospital and research equipment and supplies on-site, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and/or trainees also might participate in interactions with Industry off campus and in scholarly publications in a variety of circumstances including consulting activities of various sorts. Some aspects of these interactions can have positive effects, and are important for promoting the educational, clinical and research missions of IUSM and for translating knowledge and expertise from the faculty to society and the community. However, these interactions must be ethical and cannot create Conflicts of Interest (COI) that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. Individuals must consciously and actively separate clinical care decisions from any perceived or actual benefits expected from any company. It is not acceptable for patient care decisions to be influenced by the possibility of personal financial gain.

The IUSM Industry Relations policy (Attachment L), is therefore organized into domains drawn from the 2013 Pew Charitable Trusts report titled “Conflicts-of-Interest for Academic Medical Centers; Recommendations for Best Practices.” The domains include: Industry-Funded Speaking; Industry Support of Accredited CME; Attendance at Industry-Sponsored Lectures and Meetings; Pharmaceutical Sales Representative Presence; Medical Device Representative Presence; Curriculum on Conflicts of Interest and Extension of Policies to Community Educational Settings; Gifts and Meals; Consulting Relationships for Marketing; Consulting and Advising Relationships for Scientific Activities; Consulting or Participating with Financial Firms/Hedge Funds; Pharmaceutical Samples; Pharmacy and Therapeutics Committee; Ghostwriting and Authorship; Industry-Supported Fellowships; and Proctoring.

**Affected Stakeholders**

This policy, applies to all faculty, students, staff of the IUSM. Indiana University administrators and Trustees of Indiana University fall within the scope with regard to those policies and rules that specifically apply to them. It also applies to community members that serve on committees or in other such capacities; representatives of the IUSM such as volunteer faculty and others that speak for or on behalf of IUSM; “Investigators” on Indiana University research (as that term is defined in ACA-74); and to “dependents,” as that term is defined in Indiana Code 35-44.1-1-4, with regard to issues that fall within the purchasing, or procurement-related conflicts of interest (Indiana Code 35-44.1-1-4) and restated by Indiana University policy (FIN-PUR 3.3).
Process & Procedures

1. Annually, the Vice President and General Counsel will certify in writing to the Dean of the IUSM that the Trustees of Indiana University have received COI training.

2. Annually, the IU Office of Research Administration will collect from all “Investigators” on Indiana University research (as that term is defined in ACA-74) any significant financial interests (as so defined in ACA-74 (Attachment J) and consistent with federal regulations applicable to sponsored research) and report such interests to the IUPUI Campus COI Committee for review, analysis and follow on action. The reporting tool used for this purpose will be broad enough to collect information relevant to all financial conflict of interest issues contained in this policy. All such financial conflict of interest information will then be forwarded to the IUSM Office of the Dean for review, identification of potential conflicts and follow on COI management, as appropriate, with regard to the following:
   a. faculty outside activities (ACA-29)(Attachment c);
   b. purchasing, or procurement-related conflicts of interest that apply to all employees as well as the Trustees of Indiana University as set forth in the criminal code (Indiana Code 35-44.1-1-4)(Attachment F) and restated by Indiana University policy (FIN-PUR 3.3)(Attachment G)
   c. the standards of conduct contained in Principles of Ethical Conduct (Attachment B); the IUSM Industry Relations policy (Attachment L);
   d. such financial conflict of interest information will also be forwarded to Indiana University Institutional Review Board, or Human Subjects Office for review and follow on action by that office as deemed appropriate by its policies and procedures

3. Annually, the IUSM Office of Human Resources Administration shall engage in educational outreach efforts concerning IUSM staff compliance with:
   a. conflict of interest and conflict of commitment issues involving staff employees of the IUSM (HR-07-40 and HR-07-30) (Attachment D)
   b. purchasing, or procurement-related conflicts of interest that apply to all employees as well as the Trustees of Indiana University as set forth in the criminal code (Indiana Code 35-44.1-1-4)(Attachment F) and restated by Indiana University policy (FIN-PUR 3.3)(Attachment G)
   c. the IUSM Industry Relations policy (Attachment L)
   d. employment situations that constitute nepotism (UA-10)(Attachment H); and
   e. Principles of Ethical Conduct (Attachment B)
4. The IUSM Office of Faculty Affairs and Professional Development shall serve as a primary resource for disseminating information to faculty regarding compliance with this policy. This office will be responsible for developing and implementing a program of regular training for faculty and senior staff responsible for faculty administration regarding compliance with:
   a. faculty outside activities (ACA-29)(Attachment C);
   b. purchasing, or procurement-related conflicts of interest that apply to all employees as well as the Trustees of Indiana University as set forth in the criminal code (Indiana Code 35-44.1-1-4)(Attachment F) and restated by Indiana University policy (FIN-PUR 3.3)(Attachment G)
   c. the standards of conduct contained in Principles of Ethical Conduct (Attachment B);
   d. the IUSM Industry Relations policy (Attachment L);
   e. such financial conflict of interest information will also be forwarded to Indiana University Institutional Review Board, or Human Subjects Office for review and follow on action by that office as deemed appropriate by its policies and procedures
   f. Principles of Ethical Conduct (Attachment B);
   g. and the Indiana University Code of Academic Ethics (Attachment I).

5. Any COI management plan put in place by the IU Office of Research Administration pursuant to ACA-74 will be regularly reviewed by that office consistent with federal regulations applicable to sponsored research, to ensure compliance with ACA-74 and applicable law. Compliance plans created by the IUSM Office of Human Resource Administration or the IUSM Office of Faculty Affairs and Professional Development will be regularly reviewed by those offices, not less than annually, to determine if the plan shall remain in effect, and if so, whether it will remain in effect with or without modification.

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**Sanctions**

Enforcement of this Policy is the ultimate responsibility of the IUSM Dean’s Office. Principal responsibility for implementation and enforcement of this Policy shall reside with the University Official, advised by the relevant campus conflicts of interest committees or other campus officials with authority for conflicts matters.

Violations of this Policy and implementing procedures, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will be dealt with in accordance with applicable University policies and procedures.
Appeals from administrative decisions concerning Conflicts of Interest are subject to applicable University policies and procedures concerning review of administrative decisions.

History

1. Policy reviewed for content on November 7, 2016.
2. Policy given final approval and published on December 5, 2016.