

**University of Kansas Medical Center**  
**Conflict of Interest Procedures**  
*Version Date: January 2011*

**PROCEDURES**

**Section I. Oversight**

- A. Institutional Official: Federal law requires the appointment of an Institutional Official related to the oversight of conflict of interest. The Vice Chancellor for Administration shall serve as or appoint an Institutional Office in matters related to conflict of interest.
  
- B. Conflict of Interest Committee (COIC): A committee shall be constituted to review potential conflicts of interest, to develop management plans for real or perceived institutional and individual conflicts of interest, to advise the COI Institutional Official on matters related to conflict of interest, and to serve as a resource to faculty and staff regarding issues related to conflict of interest. The COIC shall be composed of representatives from the Kansas City and Wichita Schools of Medicine, the School of Nursing, the School of Allied Health, the School of Pharmacy, the basic sciences departments, the Office of General Counsel and the community surrounding KUMC. Office of Compliance and KUMC Research Institute staff serve as non-voting, ex-officio members. Office of Compliance staff provides committee support.
  
- C. Investigator: Investigator means the principal investigator and any other person who is responsible for the design, conduct or reporting of research, particularly research funded by PHS or proposed for such funding. In compliance with Federal requirements relating to financial interests, the term “Investigator” includes the investigator’s spouse and dependent children. For purposes of KUMC’s policy and procedures, the term “Investigator” also includes those individuals defined under “Individual Conflict of Interest” in the KUMC Conflict of Interest Policy.

**Section II. Disclosure Reporting and Review**

- A. Reporting of Disclosures: At the time of hire and annually, thereafter, at the time of reappointment, all full-time and part-time faculty and unclassified staff shall complete a Conflict of Interest Reporting Form in a manner prescribed by the Office of Compliance (see Appendix A). The reporting period lasts approximately from July 1 to mid-September. If an individual’s situation related to conflict of interest should change during the time between reporting periods, an ad hoc report shall be filed.

In addition to the classes of faculty and employees who are required to disclose conflicts of interest, as described above, any other individual who is study personnel on a research project at KUMC shall complete a Conflict of Interest Reporting Form in a manner prescribed by the Office of Compliance (see Appendix A) prior to being approved by the HSC or IACUC as study personnel.

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Institutional conflicts of interest shall also be reported in conjunction with the annual reporting period and on an ad hoc basis as circumstances warrant. Reporting of institutional conflicts of interest shall be completed in a manner prescribed by the Office of Compliance (see Appendix A).

The COI reports of institutional officials with teaching, research or patient care oversight responsibilities should be received by the COIC, or its designated representative(s). As appropriate, the COIC will request additional information, specific to an individual or institutional conflict of interest.

Individuals who serve on the HSC, IACUC, COIC, Radiation Safety Committee (RSC), Vendor Relations Oversight Committee (VROC) and the Human Stem Cell Research Oversight (HSCRO) Committee shall report on an annual basis any financial interests that might affect, or reasonably appear to affect, the scope of their responsibilities as committee members. Reports shall be made in a manner prescribed by the Office of Compliance (see Appendix A).

- B. Reporting of Disclosures Related to Financial Interests Obtained Through Licensing Agreements: When KUMC or the RI takes, or intends to take, an equity interest, stock options or any entitlement to an ownership interest in or royalty payments from a potential sponsor for research conducted at, or under the auspices of, KUMC, the president/director of the RI shall file an Equity Disclosure Form with the COIC through the Vice Chancellor for Compliance (or appropriate office responsible for oversight of the Conflict of Interest process). The Equity Disclosure Form must be signed by the president/director of the RI and the Executive Vice Chancellor of KUMC. Copies of the form shall be distributed to the appropriate department chair, director, dean or vice chancellor in a manner prescribed by the Office of Compliance (see Appendix A).
- C. Reporting of Disclosures Related to Human or Animal Research: In addition to the annual reporting period, researchers shall disclose conflicts of interest on Human Subjects Committee applications and on animal care and use protocols (ACUP).

Furthermore, any clinical trials or product testing of a KUMC, RI, KUEA or KUPI-licensed technology shall be disclosed to the HSC or IACUC and shall be subject to management by the COIC. Any such research shall be designed to minimize research discretion in interpreting results. The researcher shall maintain extensive notes to detail results and other issues that arise during the study.

- D. Reporting of Disclosures and Recusal of HSC and Other Committee Members During Deliberations: Federal regulation requires HSC members to recuse themselves from participating in any deliberations concerning or voting on protocols in which they have an interest. The IRB administrator shall poll the

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HSC at the beginning of each meeting to determine and to document in the meeting minutes whether or not HSC members have any potential conflicts of interest that would require recusal.

IACUC, COIC, RSC and HSCRO members shall recuse themselves from participating in any deliberations concerning or voting on protocols in which they have an interest.

- E. Review of Conflict of Interest Reporting of Disclosures: On a monthly basis, the COIC shall convene a meeting to review Conflict of Interest Reporting Forms in which potential conflicts are reported. The COIC also shall review conflict of interest issues referred to the committee by the HSC and IACUC.

It shall be the prerogative of the COI Institutional Official to review reports at any time and to take action on any report as appropriate per the circumstances associated with a particular real or perceived conflict of interest.

The reviewing committee shall determine whether significant competing financial interests may be managed effectively or should be eliminated. All such decisions shall be documented and shall be communicated to the individual and to his/her supervisor, as appropriate.

When the COIC determines that an official should be permitted to hold a significant financial interest in an investigational product or commercial research sponsor, even though the official will not be formally recused from research-related responsibilities, this information shall be communicated to the HSC or IACUC of record for human or animal research, respectively.

- F. Appeals Process: A COIC decision and/or action may be appealed by submitting, in writing, a request to the Associate Vice Chancellor for Compliance for review of the committee's decision and/or action. The Associate Vice Chancellor for Compliance, as Institutional Official, will review the potential conflict of interest and the committee's decision and/or action. The Associate Vice Chancellor for Compliance may then refer the matter to the COIC for reconsideration or the Associate Vice Chancellor for Compliance may make an alternate decision and/or action.
- G. Maintenance of Records: KUMC's Office of Compliance shall maintain records of all financial disclosures and actions taken by the institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, for other dates specified in 45 CFR 74.53(b) for different situations for PHS-funded research or by institutional policy for other funded research.

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**Section III. Assessing Institutional Conflicts of Interest in Research**

An institution may have a conflict of interest whenever the financial interests of the institution or of an official acting within his/her authority on behalf of the institution might affect, or reasonably appear to affect, institutional processes for the review, conduct or oversight of research.

- A. Separation of Responsibilities: To avert institutional conflicts of interest, KUMC separates the responsibilities for the ethical oversight of research from the management of certain financial interests. The function of research compliance administration is segregated from technology transfer and institutional financial interests, such as KUPI, KUEA and the RI. Additionally, institutional officials with oversight authority for research, such as deans, chairs, department and laboratory heads, and HSC and IACUC chairs, should not have responsibility for the management of the institution's investments or technology transfer program.
  
- B. Insufficiency of Separation of Responsibilities: When circumstances exist in which separation of functions is not sufficient to avoid conflicts of interest, or the appearance of conflicts of interest, the COIC will formally review the potentially conflicted relationship and assess the nature and extent of the conflict of interest. The COIC will develop a management plan for the conflict of interest, working with the institutional official and/or investigator, as appropriate.

Absent compelling circumstances and careful management of the conflict of interest, the research in question should not be conducted at, or under the auspices of, KUMC as a conflicted institution.

**Section III-1. Circumstances that *Ipsa Facto* May Create, or Appear to Create, Institutional Conflicts of Interest in Research**

Conflicts of Interest, real or perceived, are sometimes direct consequences of certain financial relationships, in and of themselves, between institutions and commercial sponsors of research. When one or more of the following circumstances exist, the COIC shall conduct a specific, fact-driven inquiry into whether or not the particular financial relationship may affect, or reasonably appear to affect, research conducted at, or under the auspices of, KUMC.

- A. Circumstances that May *Ipsa Facto* Create, or Appear to Create, Institutional Conflicts of Interest:
  - 1. When the institution is entitled to receive royalties from the sale of the investigational product that is the subject of the research;
  - 2. When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement

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to equity of any value (including options or warrants) in a *non-publicly traded* sponsor of research at the institution;

3. When, through its technology licensing activities or investments related to such activities, the institution has obtained ownership interest or an entitlement to equity (including options or warrants) in a *publicly traded* sponsor of research at the institution; or
4. When, with regard to a specific research project to be conducted at, or under the auspices of, the institution, institutional officials with direct responsibility for research (see Section IV) hold a significant financial interest in the commercial research sponsor or the investigational product. "Significant financial interest" is defined, for this purpose, as one or more of the following:
  - a. An equity interest or entitlement to equity (including options or warrants) of any amount in a *non-publicly traded* sponsor of research conducted at, or under the auspices of, KUMC,
  - b. An equity interest or entitlement to equity (including options or warrants) in excess of the *de minimis* amount (and not including exceptions for certain mutual funds) set forth by Federal and State law and Board of Regents and KUMC policies,
  - c. Consulting fees, honoraria, gifts or other emoluments or "in kind" compensation from a sponsor of research conducted at, or under the auspices of, KUMC, which in the aggregate exceed, or are expected to exceed in the next 12 months, the *de minimis* amount set forth by Federal and State law and Board of Regents and KUMC policies,
  - d. An appointment to serve, either in a personal or representative capacity, as an officer, director or board member of a commercial sponsor or research conducted at, or under the auspices of, KUMC, or
  - e. An appointment to serve on the scientific advisory board of a commercial sponsor of research conducted at, or under the auspices of, KUMC, unless the official has no current significant financial interest in the sponsor or the investigational product and agrees not to hold such an interest for a period of no less than three years following completion of any related research conducted at, or under the auspices of, KUMC.

- B. Additional Information Regarding Equity Positions: The RI may be required to divest its equity position as soon as practicable. Such a sale shall be accomplished upon the advice of the RI Finance Committee.

### Section III-2. Other Financial Relationships that May Warrant Close Scrutiny

In addition to the circumstances identified in Section III-1(A), other financial relationships with research sponsors may warrant internal or external scrutiny, depending upon the relevant circumstances. The list of other financial relationships that may warrant close scrutiny, below, is not intended to be exhaustive. As a general rule, the COIC shall

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review the financial relationships, determine the nature and degree of scrutiny required by assessing the potential for conflicts of interest and weighing the risk to research activities, and recommend a management strategy.

A. Financial Relationships that May Warrant Close Scrutiny:

1. When an investigator, research administrator or institutional official with research oversight authority participates materially in a procurement of purchasing decision involving major purchases from, or non-routine supply contracts with, a commercial entity that sponsors research at KUMC; or
2. When the institution has received substantial gifts, including gifts “in kind,” from a potential commercial sponsor of research at KUMC. Evaluation of the potential sponsor’s gift history may include the following:
  - a. Whether or not a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of research at KUMC,
  - b. Whether or not a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted, or
  - c. Whether or not any institutional official, who has the authority, by virtue of his/her position, to affect, or reasonably appear to affect, the conduct, review or oversight of the proposed research, has been involved in solicitation of the gift.

**Section IV. Assessing Institutional Officials’ Conflicts of Interest**

An official’s position may convey an authority that is so pervasive or a responsibility for research programs or administration that is so direct that a conflict between the financial interests of the individual in that position and the institution’s responsibility for the ethical conduct of its teaching, research and service missions should be considered a conflict of interest.

- A. Management of Institutional Officials’ Conflicts of Interest: To avert or mitigate institutional conflicts of interest arising from financial or other relationships of individuals in an institutional official position, conflicts of interest shall be managed by means of disclosure, recusal, monitoring of research by independent reviewers, modification of the research plan, disqualification of participation in a portion or all of the research in question, divestiture, severance of the relationship that poses the conflict of interest, or other management plan deemed appropriate to the circumstance by the COIC and/or the COI Institutional Official.
- B. Insufficiency of Management of Institutional Officials’ Conflicts of Interest: When circumstances exist in which management of institutional officials’ conflicts of interest is not sufficient, and absent other compelling circumstances, it

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shall be determined that the research in question should not be conducted at, or under the auspices of, KUMC as a conflicted institution.

**Section V. Assessing Individuals' Conflicts of Interest**

Individuals involved in teaching, research or treatment occupy positions of trust in relation to KUMC students, subjects, patients and the public. Such position obligates, by regulation, policy and ethical standards, the individual to be free of interests that compete with their teaching, research or treatment roles and could create, or appear to create, a conflict of interest.

- A. Management of Individuals' Conflicts of Interest: To avert or mitigate individual conflicts of interest arising from financial or other relationships, conflicts of interest shall be reviewed by the Office of Compliance staff and the COIC on an annual basis or as ad hoc reports are submitted. The COIC shall make recommendations for the elimination, disclosure or management of the conflict of interest.

Management may include disclosure, recusal, monitoring of research by independent reviewers, modification of the research plan, disqualification of participation in a portion or all of the research in question, divestiture, severance of the relationship that poses the conflict of interest, or other management plan deemed appropriate to the circumstance by the COIC and/or the COI Institutional Official.

- B. Insufficiency of Management of Individuals' Conflicts of Interest: When circumstances exist in which management of an individual's conflict of interest is not sufficient, and absent other compelling circumstances, it shall be determined that the research or other activity in question should not be conducted at, or under the auspices of, KUMC.

**Section VI. Research-Specific Considerations**

- A. Rebuttable Presumption Against Institutional Financial Interests in Research: When reviewing any of the circumstances that *ipso facto* may create, or appear to create, institutional conflicts of interest in research (see Section III-1), the COIC shall apply a rebuttable presumption against conduct of the research at, or under the auspices of, KUMC. The presumption may be rebutted when the circumstances are compelling and the COIC has approved an effective management plan.

Whether or not the COIC deems the circumstances to be compelling should depend in each case upon the nature of the science, the degree of risk that the research poses to subjects, and the degree to which the interests may be affected

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by the research. The COIC shall consider whether or not KUMC is uniquely qualified, by virtue of its attributes (e.g. special facilities, equipment, unique patient populations) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the subjects involved.

Even when the institution is deemed uniquely qualified, conflicts associated with significant risk to subjects should be avoided whenever possible and, if permitted, shall be closely managed.

- B. Report of Conflicts of Interest at the Time of Application to the Public Health Service (PHS): At the time that an investigator submits an application to PHS, he/she must have submitted to the Office of Compliance, by the reporting mechanism described in Appendix A, a listing of Significant Financial Interests, as well as those for his/her spouse and dependent children, 1) that would reasonably appear to be affected by the research for which PHS funding is sought, and 2) in entities whose financial interests would reasonably appear to be affected by the research.

The Office of Compliance, working with the KUMC Research Institute, will report to the PHS Awarding Component the existence of any financial conflict(s) of interest prior to any expenditure of funds under an award and will assure that the conflict(s) have been reviewed, as outlined in Appendix A, and that the conflict(s) have been managed, reduced or eliminated.

If a financial conflict of interest is identified subsequent to the award, the Office of Compliance, working with the KUMC Research Institute, will report such conflict(s) of interest and relevant plans to manage, reduce or eliminate the conflict(s) to the PHS Awarding Component within 60 days of the identification of the conflict(s) of interest.

- C. Report of Conflicts of Interest in Research to the HSC and IACUC: After reviewing a significant financial interest in research, the COIC shall communicate its conclusions, along with any management conditions to be imposed, to the HSC or IACUC having jurisdiction over the research.
1. Disclosure to the HSC or IACUC of record, to research subjects, as appropriate for human subjects research, and in all publications shall be required whenever the institution holds a financial interest that is, or could reasonably appear to be, in conflict with a proposed research project under the terms of this policy, and the conflict has not been eliminated through recusal or otherwise.
  2. The HSC or IACUC of record shall specify the form and content of the disclosure.

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- D. Multi-Center Trials: When the institution holds one of the financial interests described in Section III and any conflicts of interest cannot or will not be eliminated through recusal or otherwise managed, the presumption should be that KUMC will not conduct related research except as the non-primary site in a multi-center trial. Even when participating as a non-primary site in a multi-center trial, KUMC should not serve as the coordinating site unless the possible institutional conflicts of interest described in Section III have been managed.
- E. External Monitoring of Single/Primary Site Trials: Serving as the sole or primary performance site may be justified under compelling circumstances (e.g. when the research is an early-stage or feasibility trial *and* the expertise of institutional investigators is essential to the research). In such a case, however, the COIC should approve the circumstances, and if advisable, the research should be subject to monitoring by an oversight body with external members, such as a data and safety monitoring board.
- F. External HSC or IACUC Review: When the COIC has determined that compelling circumstances exist as described in Sections III-1(B) and V(C), KUMC should consider the desirability of contracting with an external HSC or IACUC to provide a second level of review and oversight.
- G. Subgrantees, Contractors, Collaborators: Non-KUMC individuals participating in KUMC research as subgrantees, contractors or collaborators must comply with 42 CFR Part 50 Subpart F. To demonstrate such compliance, subgrantees, contractors or collaborators must comply with KUMC's policy and procedures for reporting and managing conflicts of interest or by providing assurance to KUMC that they are in compliance with this regulation.

KUMC must then determine whether or not a conflict of interest exists on the part the subgrantee, contractor or collaborator providing assurance of compliance. If a conflict of interest exists, KUMC will work with the subgrantee, contractor or collaborator to develop a relevant management plan to manage, reduce or eliminate the conflict. KUMC will report such conflicts to the Public Health Service (PHS).

- H. Recusal: The committee that reviews financial reports of institutional officials shall have the authority to recommend that formal recusal be required when an official holds a significant financial interest in an investigational product or in an entity sponsoring research. The scope of this recusal shall include any involvement in matters or decisions that might affect, or reasonably appear to affect, the research.

Recusal is not an effective management strategy when the individual, by virtue of conflicts arising from personal financial holdings, would be precluded from fulfilling the responsibilities of his or her position. In such cases, the best interests

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of the institution may necessitate that the individual divest the interests or vacate the position.

- I. Interim Recusal: If an institutional official who holds a significant financial interest in an investigational product or commercial research sponsor becomes aware that he/she must take an action or participate in a decision that may affect, or reasonably appear to affect, the institution's research, and the official has not yet been directed by the COIC to recuse himself/herself from the matter, the official should be required to disclose the circumstances to his/her superior.

The superior may determine that recusal is necessary, may decline to require recusal or may refer the matter to the COIC for resolution. When the superior declines to require recusal, the reviewing committee should make the final determination as to whether or not recusal is necessary. In any case, the superior shall document his/her recusal determination and forward this documentation to the COIC. The COIC should maintain a central repository of information about all recusal determinations related to KUMC research.

- J. Hospital as a Separate Entity: At times KUMC's faculty, staff or students may conduct research at affiliated, yet legally separate, hospitals or clinical sites. All affiliates operating under the institution's Federal-Wide Assurance (FWA) for the protection of human subjects agree to abide by COIC policies that are the same as or no less stringent than those adopted by KUMC.
- K. Accreditation: The effectiveness of KUMC's COIC policies and a formal assessment of the institution's compliance with these policies should be examined as an element of any accreditation process for the institution's human research protection program.

## **Section VII. Enforcement**

Alleged violations of KUMC's conflict of interest policy and procedures will be reviewed by the Conflict of Interest Committee, which will determine whether or not a violation has occurred and will recommend appropriate sanctions.

Sanctions will then be referred to the KUMC Human Subjects Committee, Institutional Animal Care and Use Committee and/or the appropriate institutional official and/or department chair for implementation of the sanction(s).

For PHS-funded research, the failure of an investigator to comply with KUMC's conflict of interest policy and procedures, which results in bias in research design, conduct or reporting, will result in prompt notification to the PHS Awarding Component. The Office of Compliance, working with the KUMC Research Institute, will inform the PHS Awarding Component about the incident and the corrective action(s) taken or to be taken by the investigator and/or institution.

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Regarding clinical research, in any case in which the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by Federal regulations (i.e., 45 CFR 50), KUMC shall require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

#### **Section VIII. Conclusion**

The policy recommendations offered herein are, in some cases, more expansive than current legal requirements or standard institutional practices. KUMC strives to, maintain the public trust in the teaching, research and treatment enterprises of the institution in an open and transparent manner, and believes the preceding policies and procedures highlight that effort.

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**Appendix A**  
**Methods for Reporting of Disclosures**

- I. **Individual Conflicts of Interest:** At the time of hire and on an annual basis thereafter, individuals shall complete a Conflict of Interest Reporting Form. The form may be accessed through the Chalk training system.
- a. Once the form is completed, the individual must print out the form and submit it to their supervising director, chair or dean. The department director, chair or dean will sign the form and submit it to the Office of Compliance.
  - b. Upon receiving the hard copy forms, Office of Compliance staff will check to ensure that the form is complete and fully signed. Incomplete and/or unsigned forms will be returned to the individual for completion and/or signature.
  - c. For reports that indicate a potential conflict, the potential conflict will be referred to the Conflict of Interest Committee (COIC) for review and mitigation, as needed.

*To access the Chalk system:*

1. *Log in to myKUMC (my.kumc.edu)*
2. *Click on the Training tab*
3. *Select the appropriate Conflict of Interest module from the Chalk training list*

- II. **Research-Related Conflicts of Interest:** When submitting a human or animal research protocol for review by a Human Subjects Committee (HSC) or the Institutional Animal Care and Use Committee (IACUC), investigators must complete the Conflict of Interest sections on the respective application forms, which are posted on the HSC and IACUC Web sites. The Conflict of Interest sections must be filled out taking into consideration potential conflicts for all study personnel.

If potential conflicts are disclosed in the HSC or IACUC applications, additional information may be requested and the study will be referred to the COIC for review.

- III. **Institutional Conflicts of Interest:** On a quarterly basis, the Office of Compliance will receive a report from the Research Institute that enumerates the interests held by the institution. These interests will be reviewed by the COIC. Additionally, COI reporting forms submitted by individuals with leadership roles will be reviewed for potential conflicts of interest that may be related to their role in the institution.

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- IV. **Compliance-Related Committee Members Conflict of Interest:** At the time an individual is appointed to a compliance-related committee and on an annual basis thereafter, the Office of Compliance staff member who supports the committee will review the individual committee members' conflict of interest form. Conflict of Interest Committee members will also be queried at the beginning of each committee meeting to determine whether they have any new conflicts to report. Potential conflicts will be logged and monitored by the support staff so that individual committee members may be recused from discussions and decisions related to issues with which they may have a conflict.
- V. **Equity Disclosure Form:** When an equity interest is taken or is intended to be taken by KUMC or the Research Institute (RI), an Equity Disclosure Form must be completed and submitted to the COIC via the Associate Vice Chancellor for Compliance. The Equity Disclosure Form may be obtained by contacting the RI.