



Purpose

KDHRC strongly supports research objectivity. The Financial Conflict of Interest policies and procedures contained in this document are in place to ensure that the design, conduct, or reporting of research projects funded by external sponsors will not be biased by any conflicting financial interest. The policy establishes a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests. The policy is based on federal regulations, including but not limited to 42 CFR 50.603 and 42 CFR 50.604.

Scope

The information in this document applies to all KDHRC staffers who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored project, excluding Small Business Innovation Research Phase I grants, at KDHRC. The policy also applies to subgrantees, subrecipients, contractors, or collaborators of KDHRC involved in an externally sponsored project unless that institution or person can provide written assurance to KDHRC's president that they are subject to a similar financial conflict of interest policy.

Policies

Required training: Any KDHRC staffer who is funded by or is responsible for the design, conduct, reporting or approval of any externally sponsored project is required to complete training on this topic as a condition of employment. This training must be completed:

- Prior to engaging in research related to PHS-funded grant
- At least every four years OR
- Immediately if KDHRC revises its policy, an investigator is new to the institution, or an investigator is not in compliance with the policy.

Required disclosure: Any KDHRC staffer who is funded by or is responsible for the design, conduct, reporting or approval of any externally sponsored project is required to disclose all known Significant Financial Interests and those of his or her family members that would reasonably appear to be affected by the project. Disclosures must be completed no later than at the time of application for the research, at least annually during the period of the award, and/or within 30 days of discovering or acquiring a new significant financial interest (SFI).

Definitions¹

A Financial Conflict of Interest exists when a significant financial interest may affect the design, conduct, or reporting of the externally sponsored project. This includes situations where financial considerations may compromise or have the appearance of compromising the staffer's professional judgment to: conduct or report the research; collect, analyze, or interpret data; hire staff, vendors, or consultants; procure materials; or involve human subjects.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). **Appendix A** lists examples of possible financial conflicts of interest.

The items listed below **do not** constitute a significant financial interest:

- Salary, royalties, or other remuneration from KDHRC
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or nonprofit entities
- Any ownership interest in KDHRC held by the staffer. Ownership interest is exempt because KDHRC is a commercial, for-profit organization
- Income from investment vehicles, such as mutual funds and retirement accounts, if the staffer does not directly control the investment decisions made in these vehicles
- Salary, royalties, or other payments that are not from KDHRC and that when aggregated for the staffer and his or her family members over the next twelve months, are not expected to exceed \$5,000

Family Member means the staffer's spouse or dependent children.

Research means a systematic investigation designed to develop or contribute to scientific knowledge. The term encompasses basic and applied research and product development.

Sponsored Project means any externally funded activity which is subject to an agreement that is binding to KDHRC and commits KDHRC to a specific plan of research or scholarly inquiry.

Procedures

Training in Financial Conflicts of Interest: Any KDHRC staffer who is funded by or is responsible for the design, conduct, reporting or approval of any externally sponsored

¹ These definitions are derived from Public Health Service regulations 42 CFR Part 50, Subpart (reference 2).

project is required to complete the NIH web-based training on this topic. The training must be completed within 10 business days of hiring or promotion, and the completion certificate must be submitted to the KDHRC Human Resources Department for retention in the staffer's personnel file.

Disclosure of Potential Conflicts of Interest: As a condition of their employment, all KDHRC staffer who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored project will receive a copy of this policy and instructions on their reporting obligations upon hire and in a refresher training conducted annually at a KDHRC staff meeting. The procedures for disclosure of Significant Financial Interests are as follows:

1. *Current Projects.* Staffers participating in currently funded projects shall complete and submit a "Disclosure of Financial Relationship for Sponsored Projects" (Disclosure Form), to the president. A new Disclosure Form must be completed whenever there are any changes.
2. *Staffers added to an existing project.* Staffers added to an existing project must complete and submit a Disclosure Form to the president before they can be added to the project. No one shall be added to the project until the Disclosure Form has been reviewed pursuant to these procedures.
3. *New or Additional Financial Interests.* If any staffer or family member obtains a new or additional Significant Financial Interest, the staffer must submit an updated Disclosure Form to the president within 30 days of acquiring the new or additional Significant Financial Interest.

Review Process: The president will review each Disclosure Form to ensure that it has been properly filled out and signed by the staffer to determine the existence of any Significant Financial Interest. If the president determines that no Significant Financial Interest exists, she will file and retain the forms electronically and in hard copy. If the president determines that a Significant Financial Interest may exist, then she will appoint a Conflict of Interest Review Committee to conduct a review of the case and, as necessary, to recommend a resolution plan that places appropriate restrictions to manage, reduce, or eliminate the Conflict of Interest. The Committee shall be composed of one senior researcher on KDHRC's staff, one member of KDHRC's Institutional Review Board (IRB), a representative from KDHRC's Human Resources Department, and the president. Using publicly available guidance from NIH, the Committee will complete its review within 30 working days of receiving the Disclosure Form, and make one of the following determinations:

1. No potential or actual Conflict of Interest exists and no further action is necessary.
2. A potential or actual Conflict of Interest exists and appropriate controls already exist to manage, reduce, or eliminate the Conflict of Interest.
3. A potential or actual Conflict of Interest exists that is not adequately addressed and a resolution plan can be prepared to satisfactorily manage, reduce or eliminate the identified conflict of interest so that the staffer may participate in the research or educational project.
4. A potential or actual Conflict of Interest exists and it is not possible to implement a plan to satisfactorily manage, reduce, or eliminate the identified conflict of interest in

such a manner as to allow the staffer to participate in the research or educational project.

As necessary, the Committee will recommend a resolution plan that may include controls not limited to one or more of the following:

- a. Disclosure – disclosure includes, but is not limited to, (i) public disclosure of the significant financial interest(s) in all relevant publications and all presentations (whether or not academic presentations), (ii) disclosure to members of the project and (iii) disclosure to human subjects through informed consent
- b. Monitoring – appointment of independent reviewer(s) or independent data and safety monitoring committee or similar body to monitor the project. Monitoring may include reviewing abstracts and manuscripts before submission for publication; review of protocols, subject accrual, complications and other issues
- c. Modification – modification of the project such that the main purpose of the project is not compromised
- d. Limitation or Disqualification – limitations may include prohibiting the staffer from (i) serving as the Principal Investigator; (ii) analyzing the data; (iii) selecting or enrolling human subjects; or (iv) any other limitation capable of managing, reducing, or eliminating the conflict of interest including disqualifying the staffer from participating in the project
- e. Divestiture – allow the staffer to proceed with the project subject to the sale or disposal of all or a portion of specified financial interests to reduce or eliminate financial conflicts
- f. Severance of Relationships – requiring the staffer or his or her family member to sever relationships that create actual or potential conflicts, such as relinquishing a seat on a board of presidents or terminating a consulting agreement with an outside entity during the course of the project
- g. Any other conditions or restrictions that will contribute to the management, reduction, or elimination of the Conflict of Interest, consistent with applicable policies, regulations and laws

The Committee will submit to the president a summary report including a brief description of its findings, a clear statement of its determination and, as needed, a recommended resolution plan within 30 working days of receiving the Disclosure Form. The president will review the summary report. If the resolution plan calls for the limitation or disqualification of a staffer from a project, Human Resources will be consulted to ensure that all appropriate KDHR policies and procedures are followed. The president will meet with the staffer to discuss the determination and resolution plan. After the meeting, the staffer will receive a letter from the president stating the final determination and outlining the final resolution plan. The letter will be dated and sent no longer than 40 working days of the president receiving the Disclosure Form. A copy of the letter will be sent to the staffer's personnel file retained for at least three years.

If the staffer does not agree to comply with the resolution plan, he or she will not be able to continue working on the project and, as necessary, the president will not allow funds to be expended on the project. A staffer may appeal the resolution plan as described below.

After the appeal process has concluded or the deadline for an appeal has passed, the president will then make all necessary notifications to sponsors within 60 working days of president receiving the Disclosure Form.

Review of Projects involving Human Subjects Research: The Significant Financial Interest(s) of a staffer involved in human subject research may present real or perceived risks to the welfare of human subjects and may require additional review. If the project involves human subjects, then the Committee member from the KDHRC IRB will brief the rest of the IRB members on the project, and the IRB as a whole may then meet to provide suggestions for the resolution plan.

Appeal Rights: If the staffer disagrees with the determination or resolution plan, he or she may appeal by submitting a written request to the president for reconsideration along with any supporting materials within 10 working days from date of the determination letter. The president will review the request and supporting materials and issue a written final determination, which shall not be subject to further appeal, within 10 working days of receiving the appeal. The staffer shall sign any resolution plan required by the president before any funds will be expended under the project(s). A copy of the final determination and signed resolution plan will be retained by the president for at least three years. The president will then make all necessary notifications to sponsors.

If the staffer does not agree to comply with the resolution plan, he or she will not be able to continue working on the project and, as necessary, the president will not allow funds to be expended on the project.

Reporting: Prior to the expenditure of any funds, the president will submit an initial report to the National Institutes of Health that documents any conflicting interest found by KDHRC and assures that the interest has been managed, reduced, or eliminated. If any conflicting interest is identified subsequent to the initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated, at least on an interim basis, within 60 days of that identification. After the initial report, reporting will be annual for the duration of the project. All reports will be in accordance with federal regulations. KDHRC can update a previously submitted report if a retrospective review identifies a FCOI.

Information about FCOI held by senior/key personnel will be disclosed in each public presentation of the results of the research. If a FCOI affects previously published research, it is incumbent on the author to request an addendum to the research. Information about FCOI of senior/key personnel can be made available to the public within five calendar days of a written request submitted to the president.

Enforcement and Noncompliance

The KDHRC president or her designate is responsible for enforcement of the policy. Examples of noncompliance with this policy include, but are not limited to, failure to complete a Disclosure Form, intentionally filing an incomplete, erroneous, or misleading Disclosure Form, and failing to provide any additional information requested by the president. Failure to comply with this policy will result in the notification of the sponsor (Procedure Section G) and immediate suspension of all sponsored project funds. In addition, noncompliance may result in disciplinary action consistent with and subject to sections of the KDHRC Employee Handbook that is applicable to the employment of the staffer.

Appendix A: Examples of Significant Financial Interests

The following are examples of Significant Financial Interests that must be reported on the Statement of Significant Financial Interests Form. These examples are neither exclusive nor exhaustive of the types of significant financial interests that may be reportable. Seek guidance from your supervisor or the president if you have any questions.

- Payments (e.g., stipends, honoraria) from a sponsor, directly or indirectly, for speaking engagements when the staffer knows the source of the funding for the speaking fee. In those instances where the speaking fee is received indirectly from the sponsor, the staffer should disclose who determines the content, who selects the speakers and other factors that may assist in determining whether or not a conflict of interest exists.
- Income from service on the advisory board or scientific review panel for a for-profit pharmaceutical company that exceeds \$5,000 for the previous calendar year or is expected to exceed \$5,000 over the next 12 months from the date of completing the Disclosure Form.
- Consulting fees from any sponsor (excluding service on an advisory board or scientific review panel of a government or non-profit company) that exceeds \$5,000 for the previous calendar year or is expected to exceed \$5,000 over the next 12 months from the date of completing the Disclosure Form.
- A family member's direct ownership of stock in a publicly traded company valued at over \$5,000 that may or may not be affected by the project.
- Any payment incentives (money, gifts, other items of value) above and beyond the actual costs of enrollment, conduct of the research and reporting of the results, such as finders' fees, recruitment bonuses, enrollment bonus for reaching an accrual goal.
- Payments for protocol or study design that exceed \$5,000 in the previous calendar year or that are expected to exceed \$5,000 over the next 12 months.
- A right or expectation of obtaining a proprietary interest related to the project or related to any test article or device that will be used in the project, including any proprietary interests that the staffer may assign to any entity, including KDHRC.
- Serving as an officer or director (whether or not paid for such service) with any entity providing funds or other support to the project or in any entity that may be affected (benefited or harmed) by the results of the project (i.e., competitor, customer, collaborator or affiliate of a commercial sponsor).

- Planning to use project funds to purchase items or services from an entity in which the staffer or a family member has an interest (stock, stock options, employment, or partnership).
- Holding any partnership interest in an entity that may be impacted (detriment or benefit) by the proposed project.
 - For a publicly traded entity, the total compensation includes salary and any payment for services (consulting fees, paid authorship, etc.) and equity interest (stock, stock option, or other ownership interest) received in the twelve months preceding the date of disclosure exceeds \$5,000.
 - For a non-publicly traded entity, compensation includes salary and any payment for services received in twelve months preceding the date of disclosure exceeds \$5,000 or holding any equity interest by staffer or family (spouse or dependent children).
- Receiving payment related to intellectual property rights and interests exceeding \$5000.

HR-P-Financial Conflicts of Interest

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