



Introduction

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.

KDHRC's policy is based on federal Public Health Service (PHS) regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and an organization must take to promote objectivity in research. The regulations apply to all PHS funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants), and subawards where the originating sponsor is PHS. The regulations require that investigators submitting applications for funding, either as a prime or subrecipient, where the sponsor is PHS (e.g., funding from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control), disclose to KDHRC any significant financial interests related to their institutional responsibilities at KDHRC.

Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of KDHRC, and as defined by KDHRC in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). In this policy, "research" includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by KDHRC in the grant application, progress report, or any other report submitted to the PHS by KDHRC under this subpart.

Significant financial interest means:

- 1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a) With regard to any **publicly traded entity** a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and, the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the

- Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- b) With regard to any **non-publicly** traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) **holds any equity interest** (e.g., stock, stock option, or other ownership interest); or
 - c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests over a threshold of \$5,000.
- 2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel over the a threshold of \$5,000 (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. When disclosed, the Investigator must include details at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with KDHRC's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- 3) The term *significant financial interest* does not include the following types of financial interests:
- Salary, royalties, or other remuneration paid by KDHRC to the Investigator while the Investigator is currently employed or otherwise appointed by KDHRC, including intellectual property rights assigned to KDHRC and agreements to share in royalties related to such rights;
 - any ownership interest in KDHRC held by the Investigator;
 - income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education;
 - income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

NOTE: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local,

provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. The term “SBIR Program” also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

KDHRC’s responsibilities in regards to Investigator financial conflicts of interest

KDHRC maintains this up-to-date, written, enforced policy on financial conflicts of interest that complies with federal regulation. The policy is available on the KDHRC website and internal network files.

KDHRC informs each Investigator of KDHRC's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and requires each Investigator to complete training regarding the same, prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- 1) KDHRC revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- 2) An Investigator is newly employed by KDHRC; or
- 3) KDHRC finds that an Investigator is not in compliance with KDHRC's financial conflict of interest policy or management plan.

KDHRC takes reasonable steps to ensure that any subcontractor complies with our policy. We:

- 1) Incorporate into contracting and consulting agreements language about whose policy will apply. If the KDHRC policy applies to the subcontractor, then the subcontractor must certify that they will abide by our policy. If the subcontractor has a FCOI compliant with Federal Regulations they will certify to the same. These certifications must be completed within 20 business days of subcontract execution.
- 2) Provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subcontractor Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

KDHRC has designated a conflict of interest official (COIO) at our organization. The designated official is the President. Because the KDHRC is a small organization, we also retain the right to establish a Conflict of Interest Review Committee to conduct a review of any case in which the President is involved. 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 Chief Financial Officer.

Procedures for disclosing conflicts of interest

Prior to the submission of an application to the PHS Grantee for funding, the Principal Investigator and all other Investigators at KDHRC must have disclosed to KDHRC's President, who is the designated COIO at our Institution, an up-to-date listing of their foreign and domestic Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to the PHS Grantee for funding from the PHS Grantee, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the President promptly and prior to participation in the project.

Each Investigator who is participating in research under a prime or subaward originating from PHS must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to KDHRC, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research originating from PHS must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by the Designated Official

The KDHRC President, serving as the COIO, will conduct reviews of disclosures. The President will review any SFI that has been identified in a disclosure; these interests will be compared to the funded research on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research.

Guidelines for Determining "Relatedness" and Financial Conflict of Interest

The President will determine whether an Investigator's SFI is related to the research and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research when the President reasonably determines that the SFI:

- 1) could be affected by the research; or
- 2) is in an entity whose financial interest could be affected by the research.

The President may involve the Investigator in the determination of whether a SFI is related to the research.

A financial conflict of interest exists when the President reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to the research, and if so, whether the relationship creates a FCOI, the President considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the President may also consider the following factors:

- 1) Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
- 2) Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
- 3) Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
- 4) Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
- 5) Whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
- 6) The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
- 7) Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
- 8) The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
- 9) Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- 10) Whether other scientific groups are independently pursuing similar questions; or
- 11) Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
- 12) Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
- 13) Whether the project involves a subaward to an entity in which the Investigator has a SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the President will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the President will be guided by the principles discussed in this Policy. The President will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing

- the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;
- l) Annual reports on the research progress to the COIO/designated official.

If the President determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The President will keep a record of the disclosure and other relevant information for at least three years. If the President prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on an award or subaward supported by PHS will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the President necessary to manage the Conflict of Interest.

The President will keep a record of Investigator disclosures of financial interests and the COIO/designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant PHS Regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds from PHS, KDHC will ensure public accessibility through our website (www.kdhrc.com) or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- 1) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by KDHC in the award or subaward application, progress report, or any other report submitted to PHS;

- 2) KDHRC has determined that the Significant Financial Interest is related to the funded research; and
- 3) KDHRC has determined that the Significant Financial Interest is a financial conflict of interest.

The information that KDHRC will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

- 1) The Investigator's name;
- 2) The Investigator's title and role with respect to the research project;
- 3) The name of the entity in which the Significant Financial Interest is held;
- 4) The nature of the Significant Financial Interest; and
- 5) The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

When KDHRC uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the PHS-funded research project, if it is determined by the President that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If KDHRC responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the KDHRC's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via KDHRC's publicly accessible Web site for at least three years from the date that the information was most recently updated.

Reporting Financial Conflicts of Interest

Prior to expending any funds under a PHS-funded research project, KDHRC will provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by KDHRC to be conflicting and our management plan for that conflict.

If a new conflict is identified, KDHRC will provide within sixty days, an FCOI report regarding the financial conflict of interest and the management plan for it. The report will include this information, at a minimum:

- 1) Project number;

- 2) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- 3) Name of the Investigator with the financial conflict of interest;
- 4) Name of the entity with which the Investigator has a financial conflict of interest;
- 5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 6) Value of the financial interest
- 7) A description of how the financial interest relates to the PHS-funded research and the basis for KDHC's determination that the financial interest conflicts with such research; and
- 8) A description of the key elements of KDHC's management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance; and
- 9) KDHC will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component. The annual report will address the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists
- 10) If an interest was not disclosed in a timely manner by the Investigator or managed by KDHC, we will immediately complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, KDHC will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Training Requirements

Each Investigator must complete training on *KDHC Conflict of Interest Policy Applicable to Public Health Services Funding* prior to engaging in research related to any PHS-funded project and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1) KDHC revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators. Training is to be completed within the timeframe specified in communications announcing such changes;
- 2) An Investigator is new to KDHC research and training is to be completed prior to his/her participation in the research; or
- 3) KDHC finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy. In this case, training must be completed within 30 days in the manner specified by the KDHC President.

In fulfillment of the training requirement, KDHC requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements

and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

Clinical Research

If KDHRC determines that one of its funded clinical research projects 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 Financial Conflict of Interest that was not managed or reported by KDHRC, KDHRC shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Failure to Comply with This Policy

No expenditures of PHS funds will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any KDHRC official-approved FCOI management plan, if needed.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination, and termination of employment.