

RE-KHN

CONFLICTS OF INTEREST IN RESEARCH AND FUNDED PROJECTS

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PURPOSE:

The purpose of this policy is to reasonably ensure conflicting interests do not adversely affect the protection of human research participants, the integrity of the research, or the credibility of the research oversight program at Kettering Health Network (KHN).

DEFINITIONS:

Conflict of Interest (COI):

For the purpose of this policy, a conflict of interest describes a situation in which the existence of both personal interests and professional obligations may *affect or reasonably appear to affect* the objectivity of an individual's decision or action.

Conflict of Interest Officer (COI Officer):

The KHN Corporate Integrity Officer serves as the COI Officer. The COI Officer or designee is responsible for the review of financial interests and the determination of conflicts of interest related to research and projects subject to institutional review board (IRB) review. The COI Officer or designee is responsible to bring any questionable conflict of interest issue to the Conflict of Interest Committee (COI Committee) for determination.

Financial Interest:

For the purpose of this policy, financial interest refers to the interest of the investigator, his or her spouse and dependent children, and any entity or foundation controlled or directed by the individual or his or her spouse. A financial interest includes, but is not limited to:

- 1) Equity interests: Stocks, stock options, or other ownership interests;
- 2) Intellectual property rights and interests: Patents, copyrights, trademarks, licensing agreements, royalties, or rights to receive future royalties;
- 3) Payments: Bonuses, milestone payments, paid authorships, non-royalty payments, or payments for services;
- 4) Remuneration and gifts: Consulting fees, honoraria, gifts, endowments, income for consulting, lecturing, or serving on an advisory board, "in kind" compensation;
- 5) Sponsored or reimbursed travel, for investigators involved in any research funded in whole or in part by any U.S. Public Health Service (PHS) agency or an agency that has adopted the PHS Financial Conflict of Interest regulations;

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- 6) Positions: A position as director, officer, partner, or any other fiduciary role whether or not remuneration is received for such position;
- 7) Any arrangement whereby the value of ownership interests or the amount of compensation will be affected by the outcome of the research.

Financial interests requiring disclosure **do not** include the following:

- 1) Interests in publicly traded, diversified mutual funds or retirement accounts **unless** the investigator directly controls the investment decisions;
- 2) Income or reimbursement from a government agency, an academic teaching hospital, a medical center, an Institute of higher learning (per 20 U.S.C. 1001(a)), or its affiliated research institute **for** a) seminars, lectures, or teaching; b) service on committees / review panels; or c) sponsored / reimbursed travel;
- 3) Salary and other remuneration from KHN **if** the investigator is currently employed/appointed by KHN.

Funded research project:

Any research project funded in whole or in part by (1) an entity of KHN; (2) any federal agency; (3) a contract, grant, or agreement; or (4) a gift that is earmarked by the donor for a specific research project or a specific investigator. *Funded research project* includes any activity for which research funding is available under a PHS grant or cooperative agreement, including career development awards, individual fellowship awards, center grants, institutional training grants, infrastructure award, conference grants, and program projects. *Funded research project* also includes any research or educational activity funded by the National Science Foundation (NSF).

Institutional Responsibilities:

An individual's professional responsibilities on behalf of KHN, including responsibilities related to professional activities conducted at KHN facilities or under the auspices of KHN. Such professional activities may include medical practice, teaching, consulting, purchasing, research, institutional committee memberships, activities conducted under contracts and grants involving KHN, and service on KHN panels, boards, and foundations.

Investigator:

Any individual involved in the design, development, execution, or reporting of a funded research project or a project requiring IRB review. Investigators include, but are not limited

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to, investigators, study coordinators, subcontractors, collaborators, and other research staff. For the purpose of this policy, investigator also includes any senior/key personnel listed on a grant application or report submitted to PHS or NSF.

Public Health Service (PHS) Agencies

PHS agencies include, but are not limited to, the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Indian Health Service (IHS), Administration for Children and Families (ACF), Agency for Toxic Substances and Disease Registry (ATSDR), Office of Global Affairs (OG), or the Administration for Community Living (ACL).

POLICY:

Investigators at KHN must disclose financial interests related to their institutional responsibilities fully and accurately to KHN. Investigators involved in studies regulated by the U. S. Food and Drug Administration (FDA) must also disclose relevant financial information to the sponsor of the study. KHN will not conduct research for which the associated individual or institutional conflicts of interest cannot be managed, reduced or eliminated.

Each investigator that does not have a current financial disclosure on file with KHN for the project must complete and submit a financial disclosure to the COI Officer for:

- 1) any funded project requiring IRB review, and;
- 2) any activity for which NSF funding or PHS research funding is available.

Each investigator must complete and submit an updated financial disclosure to the COI Officer annually and within 30 days after his or her financial interest changes due to a newly acquired or newly identified financial interest requiring disclosure.

New financial disclosures must be provided to the COI Officer on or before the date of the funding application, contract proposal or IRB application. Information about project personnel and funding must also be provided to the COI Officer on or before the application date, annually, and on or before submission to the reviewing IRB or funding agency of proposed changes to project personnel or funding.

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Each investigator must complete educational requirements on financial conflicts of interest before conducting any funded research project or other project requiring financial disclosure under this policy, every four years, as required by KHN due to institutional or regulatory changes, and when required due to noncompliance with this policy or a COI management plan.

Sub-recipients who are subject to another institution's policy must provide certification that the other institution's policy complies with PHS regulations or be subject to this policy.

KHN will generally follow PHS and FDA regulations for the review and reporting of any potential, or actual, conflicts of interest that may arise in the conduct of research at all KHN facilities. If KHN finds it is unable to satisfactorily manage a conflict of interest, the funding source will be so notified.

The COI Officer or designee will review disclosures and newly identified financial interests. Results of the reviews and any management plans required will be reported to the project principal investigator and appropriate departments. If there is a disagreement, the principal investigator may appeal the decision of the COI committee to the KHN Chief Executive Officer or President through the Institutional Official or Conflict of Interest Officer. Only the KHN Chief Executive Officer or President may override the COI Committee determination.

For projects subject to IRB review, information concerning any financial conflicts of interest will be provided to the reviewing IRB. The reviewing IRB will make the final determination concerning any additional requirements necessary to manage, reduce, or eliminate conflicts of interest in order to protect research subjects. Funding for the project may not be expended and the project may not commence until all required financial reviews have been completed and any required management plans established.

KHN employees who become aware of undisclosed financial interests related to research projects should report the information promptly to Corporate Integrity. Investigators who fail to disclose financial interests related to funded research that are later determined to be conflicts of interest will be 1) subject to a retrospective review of the investigator's research activities, 2) required to complete additional COI training, 3) required to disclose the conflicts of interest in each public presentation of the research and to request an addendum to previously published presentations, and 4) may be subject to additional sanctions.

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For projects involving funding sub-recipients, this policy will apply unless the written agreement between the funding awardee and the sub-recipient specifies use of the other institution's Conflict of Interest policy and that policy complies with PHS regulations.

Financial and fiduciary relationships disclosed to the COI Officer are kept confidential to the extent required for review, reporting to federal agencies, and management of the COI.

Records pertinent to this policy must be retained for three years beyond the termination of the project, submission of the final expenditures report to the sponsoring agency, or until resolution of any actions involving the records, whichever is longer. Federal representatives will be permitted to review records pertinent to this policy for federally-funded projects at reasonable times and upon reasonable request.

Information concerning identified financial conflicts of interest held by key personnel in federally-funded research projects will be made available within 5 calendar days after receipt of a [written request](#). The request must include the name and mailing address of the person requesting the information. For PHS funded projects, KHN will provide a financial conflicts of interest report to PHS prior to the expenditure of funds, annually, within 60 days for newly identified financial conflicts of interest, and when updated subsequent to a retrospective review.

Noncompliance, Sanctions and Remedies:

Failure to comply with financial disclosure requirements or a COI management plan will be reviewed by Corporate Integrity and may result in sanctions, suspension of funding or other corrective actions. In such cases or in the event a previously disclosed financial interest was not identified as a conflict of interest, a retrospective review of the investigator's activities must be completed and documented within 120 days for PHS-funded projects. During a retrospective review, failure to provide information within 30 days when requested may result in suspension of the investigator's activity on the project or suspension of the project itself. For projects subject to IRB review, suspensions will be reported to the reviewing IRB.

If a retrospective review results in the decision that bias in the design, conduct or reporting of the project occurred, a mitigation report must be provided to PHS promptly. KHN will comply with any additional conditions or enforcement mechanisms required by PHS or NSF.

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SPONSORING DEPT: Corporate Integrity
DEPARTMENTS AFFECTED: All KHN Departments
DATE OF ORIGIN: 10/10/01
LAST REVIEWED: 5/30/06, 4/28/09, 8/21/13
LAST REVISED: 7/31/08, 6/11, 6/12, 1/16
KMC - 4/19/07; 7/12, 8/13
REPLACES: RE-KHN Conflicts of Interest in Research
and Funded Projects
APPROVED BY: Network Leadership Group (2/24/16)
Administrative Finance Council (2/24/16)
EFFECTIVE DATE: 2/24/16

References:

OHRP Final Guidance Document: *Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subjects Protection* (dated May 5, 2004)
AAHRPP Standard Reference: Element I.6.B
42 CFR Part 50 Subpart F, 45 CFR Part 94, 21 CFR Part 54
National Science Foundation Award and Administration Guide: Chapter IV
AAMC/AAU Report: *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research* (dated February 2008)

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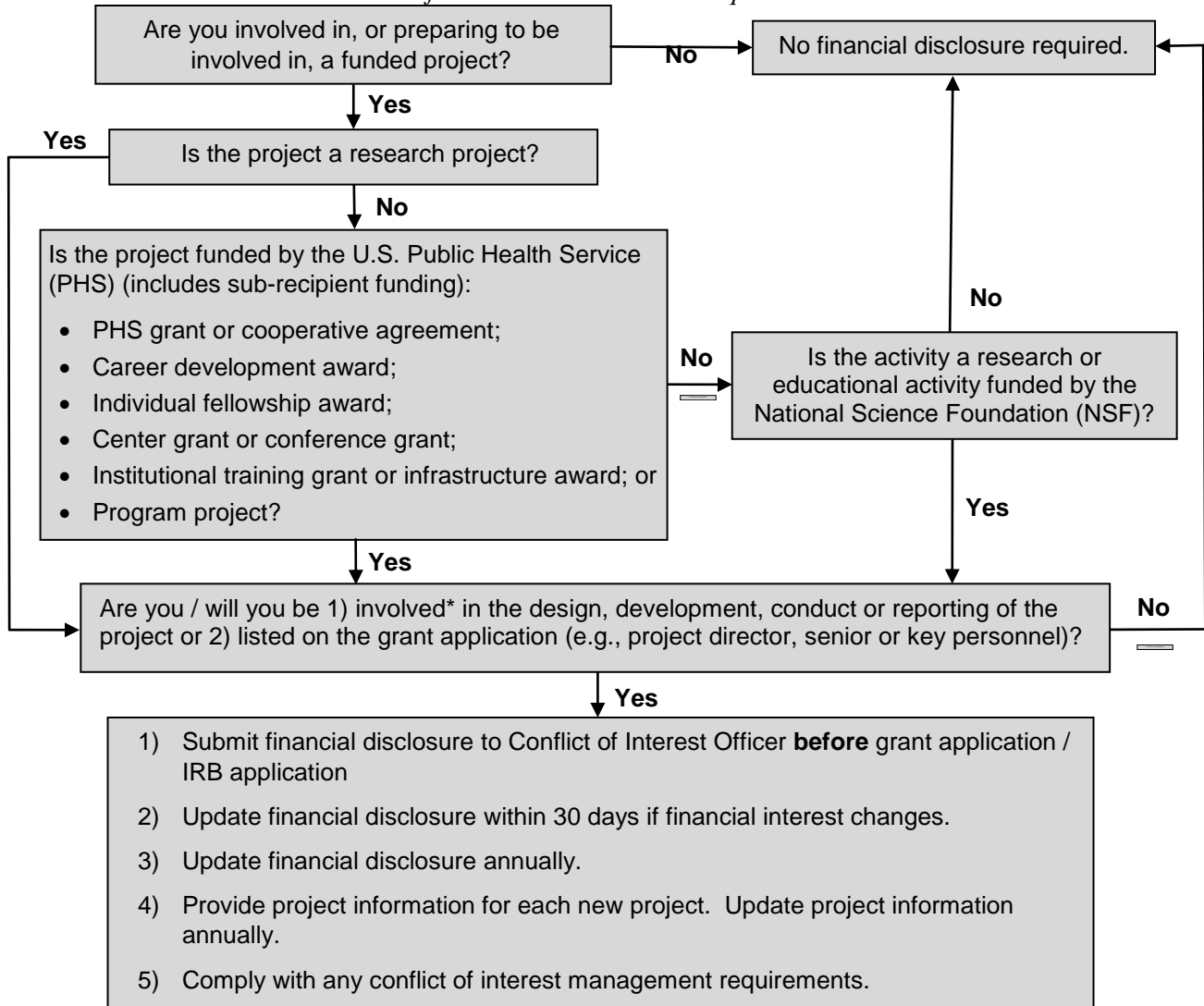
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APPENDIX A

Use this chart to determine when financial disclosures are required



* Examples of involvement:

Recruit Participants
Screen Participants
Conduct Consenting Process
Determine Eligibility
Record Medical History
Perform Physical Exam
Obtain Samples

Randomize Participants
Implant/Use Test Article
Assess Adverse Events
Monitor Data Safety
Analyze Data
Negotiate/Sign Contracts
Prepare / Evaluate Samples

Distribute/Collect Surveys
Conduct Follow-up Phone Calls
Complete Source Documents
Complete Case Rpt Forms/record data
Maintain Study Files
Maintain Tissue/Data Bank
Author, Publish, or Report Results

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