

Kessler Foundation
Policies and Procedures
Research

Subject: Financial Conflict of Interest (FCOI)
RE: Public Health Service funding requirement

Policy #: 3029A
Effective Date: December 1, 2020

Approved: 

Introduction:

This Financial Conflict of Interest policy is designed to comply with the federal regulations and hereby incorporates by reference 42 C.F.R. Part 50, Subpart F. (<https://www.ecfr.gov/>)

This policy is adopted in addition to Kessler Foundation's Conflict of Interest policy adopted January 1, 2002; revised December 1, 2008 and after August 24, 2012 it shall be utilized for all Public Health Service (PHS) research funding including the National Institutes of Health.

For a listing of PHS agencies: <http://thefdp.org/default/fcoi-clearinghouse/fcoi-agencies/>

This policy applies to all Investigators and other personnel (as defined by the policy) who are involved with PHS-funded research. The Institutional Official is responsible for ensuring implementation of this policy. Research activities may be suspended until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Kessler Foundation policy.

Purpose: To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This policy informs Investigator and Staff about situations that generate conflicts of interests related to research, provides mechanisms for Investigators and Kessler Foundation to manage any conflicts of interest that arise and how and when to report on those conflicts. Every Investigator must become familiar with, and abide by, the provisions of this policy. If a situation arises raising questions of conflict of interest, an Investigator should discuss the situation with the Institutional Official.

Applicability: To each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of Subpart F by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this Subpart F does not apply to SBIR or STTR Program Phase I application and projects. In those few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with Subpart F, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

Definitions:

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

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse or partner.

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 financial conflict of interest to a PHS Awarding Component.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, ***Financial Interest*** also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a *Financial Interest* that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or

c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or

d) is income related to intellectual property rights and interests not reimbursed through the Institution.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority 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. In terms of this Policy, KESSLER FOUNDATION is the *Institution*.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on 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.

Institutional Official or designee will be responsible for reviewing FCOI disclosure(s) and determining if a conflict indeed exists. This Official and appropriate administrative personnel will be responsible for working with the Kessler Foundation staff member(s) with the conflict and ultimately submit the FCOI report via the eRA Commons FCOI module.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS- sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

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.

Public Health Service or 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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health and the Centers for Disease Control.

Research means a systematic investigation, study, or experiment designed to 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).

Disclosure of Significant Financial Interest

All Investigators are required to disclose their outside financial interests to Kessler Foundation on an annual and on an ad hoc basis. The Institutional Official is responsible for the receipt, processing, review and retention of disclosure forms. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Investigators shall provide the following information for all Significant Financial Interests (SFIs):

Name of the entity

Nature of the financial interest

Monetary value of the financial interest or its approximate value

and any supporting documentation needed to make a determination of whether a FCOI exists.

Annual Disclosures

All Investigators must disclose their Significant Financial Interests to Kessler Foundation, through the Institutional Official or designee, at least annually during the grant period in conjunction with filing the required annual report.

Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure.

New Hires

All Investigators involved with PHS-funded research must disclose their Significant Financial Interests to Kessler Foundation, through the Institutional Official, within 30 days of being appointed or employed.

New grant proposal or subaward

Before submitting grant proposals for PHS funding or entering into subaward agreements for PHS-funded research, each Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

New Significant Financial Interest

All Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

Institutional Officer Review of Disclosures

If the disclosure is for a Significant Financial Interest as described previously, it will be reviewed by the Institutional Officer or designee to determine if the disclosure represents a Financial Conflict of Interest. If an FCOI exists then the Officer or designee will take action to eliminate, reduce or manage the conflict. It must be determined that the FCOI could directly and significantly affect the design, conduct and reporting of PHS-funded research.

If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, it will require the approval a written management plan before any related research goes forward. The affected Investigator, in consultation with the Institutional Official, is responsible for developing and submitting a proposed management plan.

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts.

If necessary, oversight committees may need to be formed for to assist the Institutional Officer in monitoring of activity on an ongoing basis and oversight of the management plan.

Reporting to PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official or designee will report in accordance with PHS regulations. If the funding for the Research is a subaward from a prime PHS-awardee, reports shall be made to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Before expending any funds under an PHS funded grant, cooperative agreement or contract, or subaward under which the prime award is funded by a PHS entity, KESSLER FOUNDATION must report to the applicable PHS funding agency (or to the prime awardee) the existence of any FCOI (as defined above) and assure that KESSLER FOUNDATION has implemented a management plan in accordance with the FCOI Regulations.

If KESSLER FOUNDATION identifies a FCOI and eliminates it prior to the expenditure of any PHS- awarded funds, KESSLER FOUNDATION is not required to submit a FCOI report to the respective agency.

Investigator Non-Compliance

Disciplinary Action

If an Investigator fails to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator and, where applicable, the IRB or IACUC, and will notify the individual of the right to appeal the decision.

Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any report previously submitted to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

Training (<https://grants.nih.gov/grants/policy/coi/index.htm>)

Each Investigator and other relevant personnel must complete training on this Policy prior to engaging PHS-funded research, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in the following situations: if this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Record Retention

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding an Investigator's research, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity that made the funding available to the Institution, if requested or required. If the Institution provides disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Public Accessibility

Prior to the expenditure of funds, the Institution will ensure public accessibility of information about any FCOI, via response to requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

The Significant Financial Interest was disclosed and is still held by the Investigator; A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest. The information to be made available shall be consistent with the requirements of the PHS policy.

Regulatory Authority

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.