

## POLICY 520

# Financial Conflict of Interest Policy Under Sponsored Projects

Responsible office: Dean of Research

Approved by: President Schuster and Board of Trustees

Authority: 42 CFR 50 subpart F and 45 CFR 94

Effective date: October 20, 2020

See also: POL 001 Code of Conduct; POL 002 Conflict of Interest Policy; POL 800 Faculty Handbook, Section IX; FORM 520A Statement of Outside Interests Related to Research; FORM 520B Conflict Management Plan Template

**THIS POLICY APPLIES TO ALL KECK GRADUATE INSTITUTE RESEARCHERS AND NATIONAL SCIENCE FOUNDATION AND PUBLIC HEALTH SERVICE FUNDED INVESTIGATORS.**

## Policy

Keck Graduate Institute (KGI) is committed to objectivity in research. We support this commitment by complying with National Science Foundation and the Department of Health and Human Services' Public Health Service (PHS) regulations requiring disclosure of Significant Financial Interests and management of all actual and perceived conflicts of interest under sponsored projects. Compliance with this Policy is a requirement for all outgoing proposals to external sponsors, and for all incoming awards from external sponsors. This Policy supplements POL 002 – Conflict of Interest Policy, KGI's general policy related to conflicts of interest and commitment.

## Purpose

The purpose of the KGI Financial Conflict of Interest (FCOI) policy and procedures is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under federal grants or cooperative agreements will be free of bias resulting from Investigator financial conflicts of interest.

More specifically, these procedures are designed to enforce the policy to identify and manage FCOI as defined by 42 CFR Part 50 Subpart F. This FCOI policy and procedures serve to:

- Promote and ensure enforcement of investigator compliance with the regulation, including requiring appropriate training of investigators
- Manage FCOI and provide initial and ongoing FCOI reports.
- Make FCOI and SFI information (including related institutional reviews and determinations) available to HHS, NSF and the public, promptly, upon request
- Ensure full compliance with the requirements of the federal regulations and KGI COI and FCOI Policies



Investigators who fail to fully and truthfully disclose actual or perceived conflicts of interest or fail to comply with any stipulated plan for managing and/or eliminating the disclosed conflict are subject to the ordinary disciplinary processes of KGI, up to and including termination of employment for cause. Such actions of an Investigator also will be considered in deliberations on contract renewal and promotions. Investigators may also be subject to criminal sanctions or civil liability under Federal or state law.

## Definitions

**Conflict Monitoring Committee (CMC):** The CMC reviews financial conflict of interest disclosures and then works with the Investigator to formulate a management plan.

**Financial Conflict of Interest (FCOI):** A financial interest that could directly and significantly affect the design, conduct, or reporting of funded research, or the performance of duties and responsibilities performed on behalf of KGI.

**Financial Interest:** Anything of monetary value or potential monetary value received from a non-KGI domestic or foreign source that reasonably appears to be related to the individual's duties and responsibilities including, but not limited to payment from a non-KGI source, travel, stock, or intellectual property.

**Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of KGI that may include research, consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards.

**Investigator:** An Investigator is any person who is responsible for the design, conduct, or reporting of research funded by external sponsors, or proposed for such funding, which may include KGI faculty, staff, graduate students, undergraduate students, collaborators, consultants, subcontractors, subgrantees and subrecipients.

**Management Plan:** A plan of action to address a financial conflict of interest, which can include reducing, manage, 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. The management plan may also include a retrospective review and mitigation report, if necessary.

**Public Health Service:** The Public Health Service (PHS) 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) or as hereafter amended.

**Significant Financial Interest (SFI):** A financial interest that reasonably appears related to the Investigator's institutional responsibilities. SFI does not include salary, royalties, bonuses or other remuneration paid by KGI directly or as assignee, income from investment vehicles such as mutual funds and retirement accounts where the Investigator does not control investment decisions, or income from review panels or advisory committees for Federal or state government agencies, or Institutions of Higher Education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

### Further definitions are included below for PHS- and NSF-specific SFIs:

**SFI under PHS:** 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:

- (1) Remuneration and/or equity interest in any publically traded entity in the twelve preceding months exceeding \$5,000 per year in value. Remuneration as used in this definition consists of salary and other payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships). Equity interest as used in this definition consists of stock, stock options, or other ownership interests.
- (2) Remuneration and/or equity interest in any non-publically traded entity in the twelve preceding months exceeding \$5,000 per year in value. Remuneration as used in this definition consists of salary and other payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships). Equity interest as used in this definition consists of stock, stock options, or other ownership interests.
- (3) Intellectual property rights and interests upon receipt of income related to such rights or interests.



(4) All sponsored or reimbursed travel regardless of the amount paid by any entity other than KGI, the state, the Federal government, an Institution of Higher Education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

**SFI under NSF:** Anything of monetary value including, but not limited to, salary or other payments for services (e.g., honoraria, consulting service fees), equity interests (e.g., stocks, stock options), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

SFI does NOT include:

- Salary, royalties or other compensation or remuneration from KGI;
- Ownership interests in a business if the business is an applicant under a Federal Phase 1 SBIR or STTR program;
- Income from seminars, lectures or teaching engagements sponsored by a public or non-profit entity;
- Income from review panels or advisory committees for Federal or state government agencies, or non-profit entities.
- An equity interest, when aggregated when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- Salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

#### **Regulatory Citations**

42 CFR 50.603

42 CFR 50.604(b), (c)(1)(i)-(iii), and (d)

42 CFR 50.604(e)(1)-(3)

42 CFR 50.604(f), (g), (h), (i), (j)

42 CFR 50.605(a)(1)-(4) and (i)-(iii), and (b)

42 CFR 50.606(a) and (c)

NIH GPS 4.1.10

**PROCEDURE 520**

# Reporting Financial Conflicts of Interest Under Sponsored Projects

See KGI Policy 520: Financial Conflict of Interest Policy Under Sponsored Projects

**Disclosure**

All Investigators are required to identify and disclose SFIs before a proposal is submitted to an external sponsor, and within 30 days of identifying a new SFI. Disclosures will be required via the Office of Research & Sponsored Projects' (ORSP) Proposal Approval Form (PAF) and emailed Conflict of Interest Disclosure. Disclosures are also required annually via KGI's Conflict of Interest Survey.

**Review**

At the time of award, KGI's ORSP Director will re-certify the SFI with the Investigator, and send an email communication to KGI's Conflict Monitoring Committee for review. If the CMC determines that a management plan is needed to eliminate or mitigate the SFI, it will work with the Investigator to create one. For federally funded awards, KGI's ORSP Director will submit an FCOI disclosure as prescribed by the regulations.

**Training**

All Investigators supported by NSF or PHS will complete FCOI training:

- Prior to engaging in research related to any NSF- or PHS-funded grant;
- At least every four years while funded;
- Immediately, if:
  - KGI revises its COI policy affecting requirements of Investigators
  - An Investigator is new to KGI or new to an externally sponsored project
  - An Investigator is not in compliance with this Policy or a prescribed management plan

The Investigator will be responsible for ensuring that all other project Investigators have undergone the required training prior to engaging in any federally funded project.



## Subrecipient Procedures

At the time of proposal, KGI's ORSP Director will request (via its Subrecipient Information Form) certification from a subrecipient institution's Authorized Organizational Representative that the subrecipient institution is in compliance with federal FCOI policies. The subrecipient institution will have the option of certifying to and following its own FCOI policy, or absent one, may elect to follow KGI's FCOI policy.

## Public Access

KGI is required to post this policy and procedure document on its website.

## Assistance

For more information, copies of relevant Federal regulations, or assistance with disclosing an SFI, please send an email to [ORSP@KGI.edu](mailto:ORSP@KGI.edu) (Office of Research & Sponsored Projects) or [COI@KGI.edu](mailto:COI@KGI.edu) (the Conflict Monitoring Committee).