

POLICY

Financial Conflict of Interest Policy Under Federal Grants

Authority: 42 CFR 50 subpart F and 45 CFR 94

Effective Date: August 24, 2012 / Revised October 30, 2020

This policy applies to all Oak Crest Institute of Science researchers and investigators funded by the National Science Foundation and Public Health Service.

POLICY

Oak Crest Institute of Science (OCIS) is committed to objectivity in research. We support this commitment by complying with the National Science Foundation's (NSF's) and the Department of Health and Human Services' (HHS's) Public Health Service (PHS) regulations requiring disclosure of significant financial interests (SFIs) 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 OCIS's general policy related to conflicts of interest and commitment.

More specifically, these procedures are designed to enforce the policy to identify and manage financial conflict of interest (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 OCIS 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 OCIS, up to and including termination of employment for cause. Such actions of an investigator also will be considered in deliberations on continuing employment and/or promotions within OCIS. Investigators may also be subject to criminal sanctions or civil liability under federal or state law.

DEFINITIONS

Conflict Monitoring: Review of financial conflict of interest disclosures and working 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 OCIS.

Financial Interest: Anything of monetary value or potential monetary value received from a non-OCIS 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-OCIS source, travel, stock, or intellectual property.

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

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 OCIS 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, managing, 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 OCIS 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 their affiliated academic teaching hospitals, medical centers or research institutes.

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 publicly 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-publicly 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 OCIS, the state, the Federal government, or an Institutions of Higher Education in the U.S. or their affiliated academic teaching hospitals, medical centers or research institutes.

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 OCIS.

- 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 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.
- 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.

PROCEDURE

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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 emailed Conflict of Interest Disclosure. Disclosures are also required annually *via* OCIS's Conflict of Interest Survey.

REVIEW

At the time of award, OCIS's Grants Manager will re-certify the SFI with the investigator, and send an email communication to OCIS's President for review. If it is determined that a management plan is needed to eliminate or mitigate the SFI, OCIS's Grants Manager and President will work with the investigator to create one. For federally funded awards, OCIS's Grants Manager 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:
 - OCIS revises its COI policy affecting requirements of investigators.
 - An investigator is new to OCIS 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.

FCOI training can be taken here:

<https://nexus.od.nih.gov/all/2018/12/03/new-financial-conflict-of-interest-training-module-available/>

Upon completion, email the Certificate of Completion to OCIS's Grants Manager (k.torguson@oak-crest.org).

SUBRECIPIENT PROCEDURES

At the time of proposal, OCIS's Grants Manager 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 OCIS's FCOI policy.

PUBLIC ACCESS

OCIS 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 OCIS's Grants Manager (k.torguson@oak-crest.org).