Dear Investigators,

NIH has recently issued guidance on financial conflict of interest (FCOI) and other support (NOT-OD-22-210). Please review this guidance carefully for requirements under the FCOI regulations as well as the University’s Policy on Financial Conflict of Interest in Research (see attached).

As a reminder, FCOI compliance is a term and condition of all NIH awards and funding.

Under FCOI requirements and the University’s Policy, Investigators must disclose their significant financial interests (SFI) and those of their spouse and dependent children, that reasonably appear to be related to the Investigator’s institutional responsibilities. This allows the University to review each disclosed SFI to determine (i) if it is related to the Investigator’s research and (ii) if the SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research. SFI that meet both criteria must be managed and reported to NIH. Investigators must receive FCOI training every four years and immediately under certain circumstances as described in the guidance.

Importantly, please note the disclosure requirement of foreign and domestic SFI related to an Investigator’s institutional responsibilities on behalf of the University. Institutional responsibilities on behalf of the University may include, e.g., activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on panels such as the University’s Institutional Review Board.

- Investigators are required to 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 foreign governments (local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure, e.g., income in excess of $5,000.

- The University’s Policy lists categories that are not SFI, including certain income from U.S. (but not foreign) institutions of higher education (See attached Policy at p.3).

If you have any questions about FCOI requirements, please contact: Terry Solomon (x7598) or Judy Wu (x8050).

Finally, please note there are different disclosure requirements for Other Support under NIH’s just-in-time procedures or in progress reports, as described in the attached guidance. If you have questions about other support reporting requirements, please refer to previous guidance from OSPA, or contact your SPO. Additionally, you can contact Collette Ryder, Director, OSPA (x8054).

Best regards,

Tim

Timothy P. O’Connor, PhD
The Rockefeller University Policy on
Financial Conflict of Interest in Research

Introduction

The objective of this Policy is to maintain the integrity and transparency of financial relationships as they may relate to Investigators’ research at The Rockefeller University (“University”). To accomplish our purpose, all Investigators (defined below) must complete an annual certification (“Annual Certification”) of their Significant Financial Interest (“SFI”, defined below) disclosures.1

This Policy is consistent with the financial conflict of interest regulation promulgated by the Department of Health and Human Services (“DHHS”), as revised in 2011 (“Regulation”), and applies to all research funded by federal Public Health Service (“PHS”) agencies as well as sponsors that follow the Regulation.2

Recipients of research funds from sources other than PHS and sponsors that follow the Regulation must comply with the conflict of interest requirements of the funding source.

Irrespective of funding source, Investigators must disclose all of their SFI, as requested, including during the University’s annual disclosure cycle. These SFI disclosures enable the University to initiate its conflict of interest review, as needed.

Investigators who are responsible for the design, conduct, or reporting of research are required to complete a certification of their SFI disclosures (“Certification”) prior to submitting a PHS grant application. Investigators are required to complete a research certification to update their SFI disclosures in connection with new research projects (“Research Certification”). Investigators also must update their SFI disclosures within thirty (30) days of discovering or acquiring any new SFI. The University’s Faculty Conflict of Interest Committee (“Committee”) determines whether the disclosed SFI is related to the Investigator’s PHS-funded research, and, if related, whether the SFI creates a financial conflict of interest (“fCOI”). If a conflict exists, assistance will be provided to eliminate, reduce, or manage the conflict.

The Rockefeller University Policy on Financial Conflict of Interest in Human Participant Research describes The Rockefeller University Hospital’s conflict of interest standard and process governing research involving human participants. Additional fCOI disclosures may be requested and requirements may be imposed by the University’s Institutional Review Board (“IRB”). For research involving human participants, fCOI disclosures may be requested and requirements may be imposed by the University’s Institutional Review Board (“IRB”).

1 During the University’s annual disclosure cycle, each Investigator will be notified by email to complete an Annual Certification. The email notification will contain a link to the Investigator’s Annual Certification workspace in the University’s Research Administration System (“RAS”). Investigators also may log into RAS at any time to complete or update SFI disclosures at: https://RAS.rockefeller.edu.

2 References in this Policy to “PHS-funded research” or “PHS awarding agency” include research funded by sponsors that follow the Regulation.
will be reviewed by the Committee and by the University’s IRB.

**Definitions**

**Investigator**
Investigator means the Project Director or Principal Investigator and any person in or collaborating or consulting with a laboratory, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

**Certification**
Certification means an Annual Certification or a Research Certification.

**Financial conflict of interest (fCOI)**
A financial conflict of interest exists when an Investigator’s SFI could directly and significantly affect the design, conduct, or reporting of the Investigator’s research.

**External Organization**
An external organization means any domestic or foreign, public or private organization (excluding a Federal agency) from/in which an Investigator (and/or his/her spouse and/or dependent children) receives remuneration or has an ownership or equity interest. External organizations include for-profit or not-for-profit companies, non-governmental organizations, foundations, and other entities.

**Significant Financial Interest (SFI)**
A significant financial interest means a financial interest consisting of one or more of the following interests, subject to the monetary thresholds below, of the Investigator (and/or her/his spouse and/or dependent children) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

1. **Payments or Remuneration** (e.g., salary, consulting fees, honoraria, paid authorship, board service payments) from an external organization, received in the 12 months prior to the date of disclosure.

2. **Equity Interest** (e.g., publicly traded or non-publicly traded stock, stock options, or other ownership interest) in an external organization, held as of the date of disclosure.

3. **Intellectual Property Payments** (e.g., royalties or other remuneration) related to intellectual property rights and interests (e.g., patents, copyrights) from any source other than the University, received in the 12 months prior to the date of disclosure.

4. **Reimbursed or Sponsored Travel** paid by an external organization in the 12 months prior to the date of disclosure. 
   - **Sponsored travel** includes travel that is paid on behalf of the Investigator but not reimbursed directly, so that the exact monetary value may not be known.
by the Investigator. In such circumstances, an estimate of the sponsored travel must be disclosed.

- Investigator disclosures must specify the purpose of the trip, the identity of the sponsor/organizer, the destination, and the trip’s duration.

Financial interest in or from any single external organization must be disclosed if the total aggregated value of payments or remuneration, intellectual property payments, reimbursed or sponsored travel, and/or an equity interest (if in a publicly-traded organization) exceeds $5,000. Note: an equity interest in a non-publicly traded organization must be disclosed regardless of the value, even if it does not exceed $5,000.

SFI does not include:
- Salary, royalties, or other remuneration from the University or Howard Hughes Medical Institute;
- Any ownership or income in mutual funds or retirement accounts so long as the Investigator does not directly control these vehicles’ investment decisions;
- Income from, or reimbursed or sponsored travel relating to, seminars, lectures, teaching engagements, service on advisory committees, honoraria, or review panels for a U.S. federal, state, or local government agency; a U.S. institution of higher education, academic teaching hospital, or medical center; or a research institute that is affiliated with a U.S. institution of higher education; or
- Payments by or ownership in an external organization that are clearly unrelated to an Investigator’s Institutional Responsibilities.

Faculty Conflict of Interest Committee (Committee)
The Committee, composed of members of the University faculty, has the authority to determine whether an Investigator’s SFI creates an fCOI. If so, the Committee works with the Investigator to eliminate, reduce, or manage the conflict by implementing a management plan.

Institutional Responsibilities
Institutional responsibilities means an Investigator’s professional responsibilities on behalf of the University which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the University’s IRB or a Data and Safety Monitoring Board.

Investigator Disclosures
Each Investigator must update his or her SFI disclosures:
- at least annually, by completing an Annual Certification;
- within 30 days of acquiring a new SFI, including reportable travel;
- within 30 days of discovering previously unreported SFI; and
- in connection with new PHS-funded research projects, or when an Investigator is added to the list of investigators on an ongoing PHS-funded research project, by
completing a Research Certification.

As a pre-condition to submitting a grant application to a PHS awarding agency, each Investigator named on the application must have completed an Annual Certification within the prior 12 months.

**Sub-Recipient Disclosures**

If research is done on behalf of the University through institutional sub-recipients, the University will incorporate, as part of a written agreement with the sub-recipient, terms that establish whether the University’s or the sub-recipient’s fCOI policy will apply to the sub-recipient’s investigators. Additionally, the written agreement should address the time frames within which the sub-recipient must provide either (i) fCOI information necessary to ensure that the University is able to meet its fCOI reporting obligations to the PHS awarding agency, or (ii) financial disclosure information to enable the University to comply timely with its review, management, and reporting obligations under the Regulation.

- If a sub-recipient defers to the University’s fCOI Policy, the individuals at the sub-recipient involved in the design, conduct, or reporting of the research are considered Investigators as defined in the University’s fCOI Policy.
- If a sub-recipient’s policy applies, the sub-recipient must certify that its policy complies with the Regulation.

**Procedures for Determining and Addressing Conflict**

No funds from a PHS awarding agency can be expended until all fCOI related to the awarded grant have been eliminated, reduced, or managed.

The Committee oversees and manages implementation of this Policy. The Committee will review each certification to determine: (a) whether a reported SFI disclosure reasonably appears to be related to the Investigator’s PHS-funded research and/or other Institutional Responsibilities, and, (b) if related, whether the SFI could directly and significantly affect the design, conduct, or reporting of the research. If the answer to both (a) and (b) is “Yes”, an fCOI may be found to exist.

If the Committee determines that the Investigator has an fCOI, the Committee will work with the Investigator on a management plan to eliminate, reduce, or manage the conflict. Management plan elements may include, but are not limited to, requiring the Investigator to disclose the potential fCOI to laboratory or study team members working on the research, to research participants, and/or to publishing journals; establishing independent review of research data; and/or requiring the Investigator to relinquish the SFI. The University will monitor the Investigator’s compliance with each imposed management plan on an ongoing basis until completion of the PHS-funded research project.

To the extent that a new or previously unreported SFI is disclosed during the course of
PHS-funded research (e.g., an Investigator who is new to the research project discloses SFI or a previously named Investigator discloses new or previously unreported SFI), the Committee will, within 60 days from the date of the disclosure, determine whether an fCOI exists, and, if so, will implement a plan to eliminate, reduce, or manage the conflict.

If an fCOI is not identified or managed as required, due to (i) a failure by an Investigator to timely disclose SFI that is later determined by the Committee to constitute an fCOI, (ii) the University’s failure to review or manage such an fCOI, or (iii) an Investigator’s failure to comply with an fCOI management plan, the University will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator’s activities and PHS-funded research to determine whether the design, conduct, or reporting of the research has been affected by bias. The University will document the retrospective review, including, at a minimum: (i) the project number and title, (ii) the Investigator’s name and the external organization creating the fCOI, (iii) the Principal Director/Principal Investigator contact information, (iv) the reason(s) for the review, (v) the detailed methodology used for the review, and (vi) the findings and conclusions. The University will notify the PHS awarding agency of any bias found in the PHS-funded research and will submit a mitigation report that addresses the impact of the bias on the research project and the University’s plan to eliminate or mitigate the effect of the bias.

The University will maintain records of all Investigator disclosures of financial interests and all actions under this fCOI Policy. Records will be kept for at least three years from the date that the final expenditure report is submitted to the PHS awarding agency, or, when applicable, as specified in 45 C.F.R. Sections 74.53(b) and 92.42(b) for different situations.

If DHHS determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by any Investigator with an fCOI that was not managed or reported as required by the Regulation, the University will require the Investigator to disclose the fCOI in each public presentation of the results of the research and to request an addendum to her or his previously published presentations.

**Reporting Financial Conflict of Interests**

Prior to the University’s expenditure of awarded funds, the University is required to report to the PHS awarding agency the existence of any fCOI, including fCOI of sub-recipient Investigator’s management plan(s) and to submit an fCOI report to the awarding agency. The University also must submit annual fCOI reports to the PHS awarding agency during the award period. These annual reports must address the status of the fCOI, e.g., whether the fCOI is being managed, any changes to the management plan, and/or if the fCOI no longer exists. Annual reports must be made for the duration of the research project period (including extensions with or without funds) in the time and manner specified by the PHS awarding agency.
The University must also submit fCOI reports to the PHS awarding agency within sixty (60) days of identifying any previously unreported fCOI.

Within five (5) business days of receiving a written request from the public for information about PHS-funded research involving an Investigator with an fCOI, the University will respond to the request in writing, providing the name of the Investigator, the external organization in which the Investigator holds SFI, the nature of the SFI, and the approximate value of the SFI, in dollar ranges, if known.

**Final University Financial Conflict of Interest Authority**

If the Committee is unable to reach agreement with an Investigator on an appropriate plan to eliminate, reduce, or manage an fCOI, the Committee will provide the Investigator with a written impasse letter. Within two weeks of the date of the written impasse letter, the Investigator or the Committee will seek the intervention of the University President.

The President will address the conflict and render a decision on its resolution. The President’s decision is final, except that it does not extend to the decisions and actions of the University’s IRB in carrying out its independent function of protecting human study participants in clinical research.

**Training**

Each Investigator must be trained on this Policy, the Investigator’s responsibilities regarding SFI disclosure, and the requirements of the Regulation. Each Investigator must complete this training (i) prior to engaging in any PHS-funded research, (ii) at least every four (4) years, and (iii) immediately, in any of the following circumstances:

- the Investigator is new to the University;
- the University revises this Policy in any manner that affects the requirements applicable to Investigators; or
- the University finds that an Investigator is not in compliance with this Policy or with the Investigator’s fCOI management plan.

**Noncompliance and Sanctions**

In the event an Investigator fails to comply with this Policy or a previously imposed fCOI management plan, the Committee shall recommend appropriate sanctions that may include, for example, imposing a stricter management plan, withholding a PHS grant application, suspending an ongoing PHS-funded research project, freezing PHS-funded research project funds, and/or other appropriate sanctions.

Financial Conflict of Interest (FCOI) and Other Support: Reminders
Notice Number:
NOT-OD-22-210

Key Dates
Release Date:
September 16, 2022

Related Announcements

NOT-OD-21-073 - Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021
NOT-OD-21-110 - Implementation of Changes to the Biographical Sketch and Other Support Format Page
NOT-OD-21-002 - Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module
NOT-OD-18-160 - Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests

Issued by
NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

Purpose:
The purpose of this Guide Notice is two fold: (1) to remind the NIH extramural research community about the longstanding requirements provided in the financial conflict of interest (FCOI) regulation at 42 CFR Part 50 Subpart F, “Promoting Objectivity in Research” (FCOI regulation for grants and cooperative agreements). This requirement also is included in the NIH Grants Policy Statement (NIH GPS), Section 4.1.10, Financial Conflict of Interest, and serves as a term and condition of NIH grant awards. This Notice reminds the extramural applicants and recipient institutions of the requirements to develop a FCOI policy, to post it on their website and submit it to NIH, to ensure Investigator disclosure of both foreign and domestic Significant Financial Interests (SFI), to review Investigator SFIs, to determine if there is a FCOI that must be reported to NIH, and to train Investigators on FCOI requirements; and (2) to remind the NIH extramural research community of the requirement to submit complete and accurate Other Support information (NOT-OD-21-073) (NOT-OD-21-110).

REMINDES

FCOI REQUIREMENTS: NIH-funded institutions are required to understand, implement, and comply with the FCOI requirements; furthermore, recipients must recognize that there are different Investigator disclosure requirements for foreign financial interests (see details below). All FCOI requirements serve as a term and condition of all NIH awards which means that compliance with the requirements is a condition of funding. An institution’s failure to comply with FCOI requirements may cause NIH to do one or more of the following: delay the issuance of awards, impose specific award conditions, or take enforcement actions to remedy non-compliance.
Throughout this Guide Notice, the term “Investigator” is used as defined by the FCOI regulation. The regulation defines “Investigator” as 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 NIH-funded research or proposed for such funding, which may include, for example, collaborators or consultants.

The information in this Guide Notice is representative of FCOI regulatory requirements as noted but is not meant to be comprehensive. Institutions should consult the regulation referenced above to identify all requirements to ensure compliance.

**APPLICABILITY OF THE FCOI REGULATION:** The FCOI regulation applies to institutions of all types, including domestic and foreign, that apply for or receive NIH research funding in the form of NIH grants or cooperative agreements. The regulation also applies to individuals who plan to participate in or that participate in NIH-funded research that meet the regulatory definition of Investigator and to subrecipient institutions and Investigators as defined above. (See: FCOI NIH FAQs).

The FCOI regulation applies to all NIH grant and cooperative agreement awards, including Phase II Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications or awards, conference grants (i.e., H13, R13, T14, and U13), resource grants, and training grants, among others. The FCOI regulation, however, does not apply to Phase I SBIR/STTR applications and awards. (See: FCOI NIH FAQs).

We would like to emphasize that NIH-funded conference grants are subject to FCOI requirements. In accordance with the NIH GPS, Section 14.6, Public Policy Requirements and Objectives, Support of Scientific Meetings (Conference Grants), conference grants are subject to public policy requirements, which includes FCOI (See 4.1.10, Financial Conflict of Interest, Public Policy Requirements and Objectives).

**OVERVIEW OF FCOI REQUIREMENTS:** Investigators must disclose their SFIs (See FCOI NIH FAQs), and those of their spouse and dependent children, that reasonably appear to be related to the Investigator’s institutional responsibilities. Institutions are required to review each disclosed SFI to determine (1) if the SFI is related to the research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research), and (2) if the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. If the institution finds that an SFI meets both criteria, the SFI is an FCOI that must be managed and reported to NIH. FCOI reports, including FCOI reports of subrecipient Investigators, must be submitted to NIH prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. FCOI reports are submitted by the recipient’s FCOI Signing Official via the eRA Commons FCOI Module.

**INVESTIGATOR TRAINING ON FCOI:** At times, institutions need to be reminded that they, and subrecipients, must provide FCOI training to each Investigator. The regulation requires Investigators to be trained prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution’s FCOI policy or management plan

Institutions are encouraged to utilize resources available on NIH’s Grants and Funding FCOI Web page found at Financial Conflict of Interest | grants.nih.gov to satisfy those training requirements related to the Federal regulation. However, Institutions must also provide additional training regarding the Institution’s FCOI policy and the Investigator’s responsibilities for disclosure of SFIs per the institution’s FCOI policy. (See NIH FCOI FAQs for more information).

**DISCLOSURE OF FOREIGN AND DOMESTIC SIGNIFICANT FINANCIAL INTERESTS PER FCOI REGULATION AND NIH GUIDANCE:** Investigators are required to disclose all foreign and domestic SFIs that are related to the Investigator’s institutional responsibilities on behalf of the Institution, and as defined by
the Institution in its policy on FCOI, 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.

NIH reminded the community of long-standing guidance in NIH Guide Notice NOT-OD-18-160 that 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 foreign governments (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). Therefore, Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibility. See NIH FCOI FAQs.

As with all Investigator SFI disclosures, the institution’s designated official(s) must review each disclosure to determine if an Investigator’s SFI(s) is an FCOI, as discussed above.

**FCOI POLICY REQUIREMENTS AND SUBMISSION OF FCOI POLICY TO NIH:** Each institution that is subject to the FCOI regulation is also required to maintain an updated, written, enforced policy on FCOI that complies with the regulation. Institutions must make the policy available via their respective publicly accessible website.

On September 30, 2020, NIH issued a Guide Notice NOT-OD-21-002, “Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module” (IPF Module). NIH funded institutions are required to submit their publicly accessible FCOI policy to NIH via the eRA Commons IPF Module. A PDF of the FCOI policy must be submitted by the institutional signing official (SO). The information is provided on an institutional level as part of an institution’s IPF, rather than on a grant-specific level, so it is not necessary to submit the FCOI policy with each grant application.

Institutions may utilize the “FCOI Policy Development Checklist” to develop, revise, or review an Institution’s FCOI policy to determine compliance with the FCOI regulation. The checklist, FAQs, presentations, and many other resources, are posted on NIH’s Grants and Funding FCOI webpage at https://grants.nih.gov/grants/policy/coi/index.htm.

**OTHER SUPPORT DISCLOSURE REQUIREMENTS:** Institutions are reminded that information submitted to the NIH on other support for identified senior/key personnel under NIH’s Just-in-Time Procedures or in Progress Reports must include all resources made available to senior/key personnel in support of and/or related to all their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant, which includes resources and/or financial support from all foreign and domestic entities. As noted in NOT-OD-21-073 NIH requires supporting documentation, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts, grants, or other agreements are not in English, recipients must provide translated copies.

In an effort to remind the community of where to disclose and report on other support and FCOI requirements, NIH has provided a NIH Disclosures Table to outline, by activity, what is and what is not required to be disclosed.

**Inquiries**

Please direct all inquiries to:

FCOI inquiries may be submitted to:
Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration, OER
Email: FCOICompliance@mail.nih.gov

Other Support disclosure policy inquiries may be submitted to:

Division of Grants Policy
Office of Policy for Extramural Research Administration, OER
Email: GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices