

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 an Annual Certification of their SFI disclosures 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. 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

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.

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.

As amended by the Academic Council on April 17, 2012, effective August 24, 2012 and reported to the Board of Trustees on June 6, 2012, and as further amended by Academic Council on April 18, 2016 and May 16, 2017.