

The Rockefeller University Policy on Financial Conflict of Interest in Human Participant Research

Introduction

The objective of this Policy is to maintain integrity and transparency of financial relationships as they may relate to Investigators' human participant 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 applies to all human participant research conducted at the University.² 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 involving human participants are required to complete an Annual Certification of their SFI disclosures prior to submitting a protocol for review by the University's Institutional Review Board ("**IRB**"). Investigators are required to complete a Research Certification to update their SFI disclosures in connection with new research protocols on which they are Key Study Personnel ("**KSP**") (defined below). Investigators also must update their SFI disclosures within thirty (30) days of acquiring or discovering any new SFI. The University's Faculty Conflict of Interest Committee ("**Committee**") determines whether the disclosed SFI is related to the Investigator's 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. By requiring the routine completion of financial disclosures, the University expects that studies will not be withheld from submission or timely IRB review/approval due to a disclosure failure.

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 The Rockefeller University Policy on Financial Conflict of Interest in Research applies to all research funded by federal Public Health Service ("**PHS**") agencies as well as sponsors that follow the PHS financial conflict of interest regulation promulgated by the Department of Health and Human Services, as revised in 2011 ("**Regulation**"). Investigators conducting human participant research funded by a PHS agency or a sponsor that follows the Regulation must comply with the requirements of both this policy and the aforementioned conflict of interest policy. Recipients of research funds from sources (other than PHS agencies or sponsors that follow the regulation) that impose the funder's own conflict of interest requirements must comply with those requirements in addition to those of the University.

Definitions

Investigator

Investigator means any KSP regardless of title or position, who is named on a study protocol involving human participants.

Key Study Personnel (KSP)

All persons who are responsible for the design, conduct, or reporting for the study.

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 a protocol involving human participants:

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**, 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**.

In addition, an Investigator must disclose his/her inventorship of any drug, device, or method that is to be used in research involving human participants and on which the Investigator is a KSP.

SFI does not include:

- Salary 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.

Procedures for Financial Disclosure and For Addressing Conflict

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
- prior to submission of a protocol to the IRB, or when an Investigator is added to an ongoing protocol as KSP, by completing a Research Certification.

The Committee will review each certification to determine whether a reported SFI disclosure reasonably appears to be related to the Investigator's research and, if related, whether an fCOI exists. The Committee will propose a management plan and promptly report the plan to the University's IRB. The IRB may alter or enhance the Committee's proposed plan. No research protocol involving human participants can be approved until all Investigators' fCOI related to the protocol have been eliminated, reduced, or managed.

If previously unreported SFI is discovered during the course of a study involving human participants, the University must undertake a documented audit to determine whether an fCOI exists and, if so, whether the research has been affected by bias. If there is evidence of bias, a report of this activity and steps taken to address the findings must be submitted to the IRB, cognizant agencies, and sponsors. Additional corrective and disclosure measures may be required.

Training

Each Investigator on a study involving human participants is required, pursuant to AAHRPP guidance, to complete fCOI training prior to engaging in such research and to be retrained at least every four (4) years.

Adopted by Academic Council on October 7, 2013, and as further amended by Academic Council on May 17, 2016 and May 16, 2017; technical correction approved by Faculty Conflict of Interest Committee and presented to Academic Council on January 25, 2019.