

The Rockefeller University Policy on Financial Conflict of Interest and Conflict of Commitment in Research

Financial Conflict of Interest

Introduction

The objective of this Policy is to maintain the integrity and transparency of financial relationships related to investigators' research at The Rockefeller University. To accomplish our purpose, all investigators (defined below), regardless of title or position and irrespective of funding source, are expected to complete a Significant Financial Interest Disclosure Form at least annually, disclosing all of their Significant Financial Interests ("SFI") (defined below).

Investigators who are responsible for the design, conduct, analysis or reporting of research are required to disclose their SFI prior to submitting a federal Public Health Service grant application. By requiring all investigators routinely to complete financial disclosures, the University can assure that no grant will be withheld from submission due to a disclosure failure.

Investigators must update disclosures within thirty (30) days of discovering or acquiring any new SFI.¹ If an investigator's Significant Financial Interest Disclosure Form reflects a financial conflict of interest, assistance will be provided to eliminate, reduce or manage the conflict.

Conflicts in research involving human participants will be managed differently than conflicts arising in other research.²

Definitions

The University definitions of the following terms track the federal regulatory definitions.

Financial conflict of interest

A financial conflict of interest exists when an investigator's Significant Financial Interest could directly and significantly affect the design, conduct, analysis or reporting of the investigator's research.

Significant Financial Interest

¹ This disclosure will not substitute for the required statements that accompany Institutional Review Board filings. Howard Hughes Medical Institute (HHMI) Investigators will continue to meet separate HHMI disclosure requirements. Recipients of research funds from other sources must comply with the conflict of interest requirements of the funding source.

² The Rockefeller University Human Research Protection Program describes the Hospital's conflict of interest standard and process governing research involving human subjects.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator (and her/his spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities:

1. Publicly traded entities: (a) remuneration (e.g., salary, consulting fees, honoraria, paid authorship) from the entity in the 12 months prior to disclosure; and/or (b) equity (e.g., stock, stock options, other ownership interest) held as of the date of the disclosure that (c) when combined (remuneration + equity) exceeds \$5,000;
2. Non-publicly traded entities: (a) all remuneration from the entity in the 12 months prior to disclosure that, when combined, exceeds \$5,000 and/or (b) any equity interest in the entity;
3. Receipt of income in excess of \$5,000 received in the 12 months prior to disclosure through intellectual property rights and interests (e.g., patents, copyrights) from any source other than the University or HHMI;
4. Travel: any reimbursed or sponsored travel (i.e., that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), but not including travel reimbursed or sponsored by: a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Significant Financial Interest does not include

- Salary, royalties or other remuneration from The Rockefeller University or HHMI;
- Income from investments such as mutual funds or retirement accounts so long as the investigator does not directly control these vehicles' investment decisions; or
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels for a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Investigator

Investigator means any person in or collaborating or consulting with a laboratory, regardless of title or position, who is responsible for the design, conduct, analysis or reporting of research.³

³ If research is done on behalf of the University through institutional subrecipients, subgrantees, subcontractors, consultants or collaborators, those institutions having a written agreement with the University must ensure that the institution (i) has a written, enforced financial conflict of interest policy that

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 Institutional Review Board or a Data and Safety Monitoring Board.

Procedures for Financial Disclosure and For Addressing Conflict

Prior to the submission of a grant application to the Public Health Service (most commonly to the National Institutes of Health), each investigator named on the grant must have filed, within the preceding 12 months, a Significant Financial Interest Disclosure Form and an interim update, if and as needed (see below).⁴ Completed forms will be reviewed by the administrative office for the Faculty Conflict of Interest Committee ("FCIC"). No federal funds awarded can be expended until all financial conflicts of interest related to a grant have been eliminated, reduced or managed.

The Faculty Conflict of Interest Committee manages implementation of the University's financial conflict of interest policy. The FCIC, appointed by the President on the advice of Academic Council, is composed of three tenured faculty members who serve staggered three-year terms. It is expected that in the third year of a member's term, that member will act as Chair of the FCIC.

Each Significant Financial Interest Disclosure Form will be reviewed to determine whether reported SFI reasonably appear to be related to the investigator's research and other institutional responsibilities and, if so, whether a financial conflict of interest exists. The FCIC will work with an investigator who has a conflict to secure his or her agreement to eliminate, reduce or manage the conflict.

In addition to reporting Significant Financial Interests at least annually, investigators must update SFI disclosures within thirty (30) days of acquiring new SFI or discovering previously unreported SFI. If new SFI creates a conflict of interest, a plan to eliminate, reduce or manage the conflict must be put in place. If previously unreported SFI is discovered during the course of federally-funded research, the University must undertake a documented audit to determine whether conflict of interest is present 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 National Institutes of Health or other Public Health Service granting agency.

is compliant with federal requirements, or (ii) in the absence of a written enforced policy, the institution will comply with applicable federal mandates.

⁴ Financial Disclosure Forms and Updated Financial Disclosure Forms will be available on the University's website at <http://mycoi.rockefeller.edu/>. These Forms will be accessible on line and can be completed and submitted electronically.

Within five (5) business days of receiving a written request from the public for information about federally-funded research involving a conflicted investigator the University will respond to the request in writing, providing the name of the conflicted investigator, the entity in which the investigator holds SFI, the nature of the SFI and the approximate dollar value of the SFI, in dollar ranges, if known.

Federal regulations further provide that when a financial conflict of interest is not timely identified or managed due to an investigator's disclosure failure or to the University's conflict management failure, a documented institutional audit of the investigator's activities must be undertaken by the University to identify any bias in the design, conduct, analysis or reporting of the investigator's research. The University must notify the federal granting agency of any bias found in the funded research and submit a mitigation report. Additional corrective and disclosure measures may be required.

Final University Conflict of Interest Authority

If the FCIC is unable to reach agreement with an investigator on an appropriate conflict elimination, reduction or management plan, the FCIC will provide the investigator with a written impasse letter. Within two weeks of the date of the written impasse letter, the investigator or the FCIC shall seek the intervention of the University President.

The President will address the impasse as he determines appropriate. The President's decision on the conflict and its handling is final, except that this final authority does not extend to the decisions and actions of the Institutional Review Board in carrying out its independent function of protecting human study participants in clinical research.

Training

Federal regulations obligate each investigator to complete training in the new requirements prior to engaging in federally-funded Public Health Service research. Every University investigator is also required to be re-trained on the regulations at least every four years.

Conflict of Commitment in Research

This conflict of commitment in research policy has been adopted by the University and is not subject to external requirements.

Investigators' external activities should not interfere with the primary professional commitment of their time and intellectual energies to the education and research programs of The Rockefeller University.

Up to 52 days per year may be devoted to external activities provided that an investigator's University work is not adversely affected. Government service and service with not-for-profit institutions do not count against the guideline stated here.

University doctoral students and postdoctoral appointees are not permitted to engage in extramural activities for compensation.

Requests to engage in activities outside of these guidelines should be addressed to the President or his or her designee and may be approved if extraordinary circumstances warrant.

Consulting arrangements with outside entities cannot compromise the University's rights to intellectual property as established in University policy.

Entities outside the University may not impose restrictions on investigators' rights to disseminate results of research performed at the University in published or other form, except for reasonable delays not to exceed ninety (90) days to allow for patent processing.

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.