

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

[June 7, 2006]

## **Introduction**

The objective of this Policy is to maintain the integrity and transparency of financial and fiduciary relationships related to investigators' research at The Rockefeller University. Attention to this principle will support the integrity of the science done by this University. The commitment of the community will be required to achieve our goal.<sup>1</sup>

To accomplish our ends, the University will require that all Heads of Laboratory complete an annual Financial Disclosure Form.<sup>2</sup> Investigators will update disclosures between annual submissions to reflect material changes in information previously provided. The financial interests that must be disclosed are only those that relate to holdings relevant to an investigator's research. If an investigator's disclosure statement reflects conflict, assistance will be provided to reduce the conflict and to manage that which persists.

Federal regulations require that significant financial interest must be declared at the time of a grant application and, in the event a conflict exists, an investigator must have signed a conflict management plan prior to the expenditure of federal grant monies. Prior to submission of a grant, each "key person" on the grant must disclose to the University his or her relevant financial holdings. A key person is anyone named on the grant application who is responsible for the design, or the conduct, or the reporting of the proposed research. Failure to make such declaration will prevent the grant submission, and failure to agree to management of a conflict means that awarded funds cannot be spent. This Policy applies the same disclosure requirement to all grant applications, irrespective of funding source.

If research is done on behalf of the University through subgrantees, contractors, subcontractors, or collaborators, those institutions having a written agreement with the University must ensure that the institution (i) has in effect a written, enforced policy on conflict of interest that is in compliance with applicable federal law and regulations, or (ii) in the absence of such a policy, will comply with the applicable federal mandates.

Disclosure of financial interests creating a conflict will not impose a bar to science. It will merely occasion the need for appropriate management. Conflicts in research

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<sup>1</sup> This policy covers and applies to Heads of Laboratories, Associates and Assistant Professors, Research and Senior Research Associates, and Post Doctoral Investigators.

<sup>2</sup> 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, additional, HHMI disclosure requirements.

involving human participants will be managed differently than conflicts arising in other research.<sup>3</sup>

## **Summary of Policy**

An investigator has a conflict of interest where his or her significant financial interest (defined below) and/or position as a fiduciary/manager in an entity could directly and significantly affect the design, conduct, analysis or reporting of research.<sup>4</sup> To determine whether there is such a conflict, an investigator will report all those financial interests and fiduciary positions that are relevant to the investigator's research (e.g., the investigator holds equity in a company whose product is being clinically tested by the investigator, or the investigator is an officer of a company whose current or future valuation or profits could be affected by the investigator's research). All relevant interests must be disclosed so that a finding may be made whether there is a conflict. If a conflict exists, it must be eliminated, reduced or managed so that the investigator's research may go forward.

## **Conflict of Interest**

The University defines conflict of interest as follows:

**A conflict of interest exists when an investigator's significant financial interest in or position as a fiduciary of an entity could directly and significantly affect the design, conduct, analysis or reporting of research.**

The University's definition is the same as the federal government's, with the addition of the fiduciary element. The standard requires (i) holding a significant financial interest (defined elsewhere in our policy, see below) or a fiduciary position<sup>5</sup>, (ii) the apparent possibility of an effect on research, and (iii) the requirement that such perceived potential effect be direct and significant.

## **Significant Financial Interest**

The University's definition of a significant financial interest is, again, consistent with the federal government's.

**Significant Financial Interest is anything of monetary value acquired or held by the investigator and her or his immediate family (spouse and dependent**

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<sup>3</sup> The Rockefeller University Hospital Standard Operating Procedures describe the Hospital's conflict of interest standard and process applicable to research involving human subjects.

<sup>4</sup> The University's intellectual property policy at: <http://www.rockefeller.edu/techtransfer/IPPolicyFINAL.pdf> imposes further restrictions on an investigator's opportunity to hold a fiduciary position.

<sup>5</sup> A fiduciary is defined as an officer, trustee, partner, board member (but not a Scientific Advisory Board member), or other person who acts in the role of a principal for an entity.

**children) including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights) with the exception of:**

- 1. Salary, royalties, or other remuneration from Rockefeller or HHMI, or**
- 2. An equity interest in a privately-held or publicly-traded company that when aggregated, is both not more than \$10,000 and is not more than a 5% ownership interest; or**
- 3. Salary, royalties or other payment obligations or expectations from a single entity that when aggregated for the next twelve months are not expected to exceed \$10,000.**

### **Circumstances Creating a Conflict of Interest**

The following circumstances may create a conflict of interest requiring a management plan:

- Research (1) funded by or (2) involving a method, product or service owned by or licensed to an entity in which the investigator has a Significant Financial Interest.
- An investigator's fiduciary position in a company that funds his or her research or that owns or has a license for a method, product or service used in the investigator's research.

### **Procedures for Managing Conflict**

A Faculty Conflict of Interest Committee ("FCIC"), appointed by the President with the advice of the 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.

Annual Financial Disclosure Forms will be submitted to the FCIC by all persons to whom this policy applies. The FCIC will explore with each investigator whether his or her disclosure reveals a significant financial interest that creates a conflict of interest. If so, the FCIC will secure the investigator's agreement to the University's standard conflict of interest management plan. Information received or explored in this process will be closely held with dissemination governed by a need to know.

The elements of the University's standard conflict of interest management plan follow:

- An investigator should disclose his or her conflict-generating association(s) to all members of the investigator's laboratory.

- An investigator should disclose his or her conflict-generating associations to the Faculty Advisory Committee of any student working on research sponsored by and/or involving a method, product or service owned by or licensed to a company in which the investigator has Significant Financial Interests. The Faculty Advisory Committee should review annually whether the design of research on which such a student is working is suitable for fostering the student's academic development. A copy of this aspect of the investigator's management plan will be sent to the FAC so that annual review can occur without further process.
- In connection with a manuscript, an investigator should abide by the conflict of interest disclosure requirements of the publishing journal.
- In connection with a presentation, an investigator should abide by the conflict of interest disclosure requirements of the organization sponsoring the presentation.
- When submitting a new, re-submission or continuing grant application, an investigator should update his or her annual Financial Disclosure Form if circumstances have changed since the most recent disclosure. The grant application cannot be submitted if financial disclosure has not been made.
- When submitting a clinical protocol to the Institutional Review Board, an investigator is required to comply with the conflict of interest elements of The Rockefeller University Hospital Standard Operating Procedures.

If an instance arises where the FCIC is unable to reach agreement with an investigator on a management plan, the FCIC will declare to the investigator in writing an impasse. Within two weeks from the date of the written declaration, the investigator or the FCIC may seek the intervention of the President in the event of an impasse. The FCIC and the investigator must act with dispatch so that the investigator may engage in her or his scientific work with the conflict issue resolved. In accordance with federal law, prior to the expenditure of any funds under a federal award, a conflict of interest related to research under a funded grant must be managed.

#### Final Conflict of Interest Authority

The President will address the impasse as he determines appropriate. The President's decision on the issue of conflict and its management 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.

## **Conflict of Commitment**

This policy is self-imposed 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 Rockefeller University.**

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

**Rockefeller 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 patent 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 days to allow for patent processing.**

As amended by the Academic Council on May 23, 2006,  
and reported to the Board of Trustees on June 7, 2006.