

University of Rochester

Policy

Faculty Conflict of Commitment and Interest

PROLOGUE*

The integrity of the University as a community of scholars requires the open exchange of ideas in an atmosphere free from commercial conflict and influence. Therefore, the university must ensure that reports of research and scholarship can be disseminated on an open and timely basis without externally imposed requirements of restriction or review, in keeping with long-honored academic traditions. To this end, all members of the university community are expected to be open about any involvements with, and obligations to, external parties that could be interpreted as leading to such restrictions. This is especially important in those cases where relationships with external parties could lead to personal financial benefit from their scholarly work or ideas, or from the scholarly work or ideas of colleagues, including students, staff and faculty.

The primary intent of this policy is to help research faculty more effectively manage potential conflicts in the course of their University activities. By reporting financial interests and managing conflicts from the start, the University and the researcher can work together to prevent outcomes that may be harmful to either the researcher or the University at large. Further, this policy fulfills federal grant requirements to report certain financial interests.

INTRODUCTION

This statement contains The University of Rochester's ("UR" or "University") policies and procedures governing conflict of commitment and conflict of interest. These policies apply to all members of the UR faculty, students, post-doctoral fellows, residents, and staff, unless otherwise excluded. School deans or University counterparts, or their designees, are responsible for ensuring implementation of these policies and may suspend all relevant activities until the conflict of interest is resolved or other action deemed appropriate by the Provost is implemented. Violation of any part of these policies may, in extreme cases, constitute cause for administrative action as described in the Faculty Handbook.

Financial conflicts of interest are common and often unavoidable in a modern research university. They can arise from the fact that one mission of the University is to promote the public good by fostering the transfer of knowledge gained through University research and scholarship to the broader world, which includes the private sector. Two important means of accomplishing this mission are faculty consulting and the commercialization of technologies derived from faculty research. It is appropriate that faculty be rewarded for their participation in these activities through consulting fees and sharing in royalties and other financial devices resulting from the commercialization of their work. It is not appropriate, however, for an individual's professional objectivity to be affected by considerations of personal financial gain.

While this policy addresses the management of conflicts of interest for faculty, the University also has an obligation to ensure that its own financial interests are not inconsistent with or detrimental in any way to its core missions.

* Words and phrases that appear in *italics* are defined in the Definitions section of the policy.

DEFINITIONS

“*Clinical trials*” refers to all research studies that involve both interaction with human subjects and the concurrent use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

“*Confidential information*” refers to confidential information of the University. It includes, but is not limited to, medical, personnel, or security records of individuals; proprietary knowledge about anticipated material requirements or price actions; and proprietary knowledge of possible new sites for government operations or information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements.

“*Conflict of Interest Committee*” refers to the University committee that advises the Deans and Provost on conflict of interest matters. The committee consists of at least five full-time faculty members appointed by the Provost, and others as deemed appropriate by the Provost. The Director of the Office of Research and Project Administration (ORPA) serves as an ex-officio, voting member of the committee. The Director of the Office of Technology Transfer and the Chief Technology Transfer Officer of the Medical Center serve as ex-officio, non-voting members of the committee. Ad hoc members can be added at the direction of the committee. The Provost serves as an ex-officio, non-voting chair of the committee.

“*Dean*” refers to a school’s senior academic dean or counterpart (such as Director of the Laboratory for Laser Energetics). When this policy refers to the responsible *Dean* in cases where the *faculty* member has appointments in more than one school within the University, the responsible party is then the *Deans* (or counterparts) of each school. (In all cases that make reference to a conflicted or potentially conflicted *faculty* member, if that *faculty* member is the *Dean*, the relevant decision-maker is the Provost or Senior Vice President for Health Sciences, as appropriate.)

“*Faculty*” refers to all individuals holding an academic, clinical, or research appointment of half-time or more with the University. While the conflict of interest policy is directed toward *faculty*, the general guiding principles should be applied to all University personnel.

“*Family members*” refers to members of the immediate family, specifically dependents, spouses, and domestic partners.

“*Investigator*” refers to the principal *investigator(s)* (PI), *co-investigator*, and any other person (e.g., post-doctoral fellows, senior scientists, graduate students) who is responsible for the administration, design, conduct, or reporting of sponsored research; research involving the use of University resources that are not generally available to the University community; internally funded research that involves human subjects; or proposals for funding. This definition is not limited to those titled or budgeted as *investigator* on a particular proposal. Students and other relevant personnel may be considered *investigators* where, in the judgment of an academic advisor or relevant supervisor, the student or other personnel is working relatively autonomously and should be considered an *investigator*.

“*Significant financial interest*” means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); any equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, trademarks, servicemarks, copyrights, and royalties from such rights). For individuals not involved in human subject research, a *significant financial interest* includes:

- a) salary, royalties or other payments for services if, when aggregated for the individual and *family members*, is expected to exceed \$10,000 from any single source for any 12-month period;

- b) equity interest if, when aggregated for the individual and *family members*, exceeds \$10,000 in value as determined by a reasonable measure of fair market value or exceeds one percent ownership.

For individuals involved in human subject research, any salary, royalties, or payments for services accruing to the individual or *family member*, or equity interest held by the individual or *family member*, when the payments or equity interest affect, appear to affect, are affected by, or appear to be affected by, the individual's research involving human subjects, is considered to be a *significant financial interest*.

Significant financial interest does NOT include:

1. salary, royalties, or other remuneration from the University of Rochester;
2. income from the authorship of academic or scholarly works;
3. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. income from service on advisory committees or review panels for public or nonprofit entities;
5. equity managed by an unrelated, unbiased third party (e.g., invested in a mutual fund); or
6. equity interests and/or remuneration that does not affect, appears not to affect, is not affected by, and appears not to be affected by, the *faculty's* teaching, research, clinical, administrative, or other University of Rochester activities.

GENERAL PRINCIPLES

Conflict of Commitment:

Conflicts of commitment are to be avoided because they detract from the educational and research process and may generate disputes between *faculty* and the University over intellectual property ownership. A conflict of commitment exists when a *faculty* member's outside activities (e.g., consulting, pro bono or public service work) interfere with his or her ability to meet the research, educational, service, and administrative responsibilities of his or her faculty appointment.

Faculty responsibilities may depend on whether the appointment is full- or part-time and may vary across schools and departments, but should be agreed upon between the *faculty* member and department chair. *Faculty* must commit their professional and intellectual allegiance and energies to the University as specifically defined in the University's Policy on Faculty Consulting.

If a situation raising questions of conflict of commitment arises, a *faculty* member should discuss the situation with his or her department chair and school *Dean* as required by this policy.

Conflict of Interest:

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University and its constituents. The conflict may be either actual or apparent – apparent conflicts of interest arise in circumstances in which an independent observer might reasonably question whether the individual's professional objectivity in that situation is affected by considerations of financial gain.

The goal of the policy is to avoid or to manage situations that call into question the credibility and objectivity of the research and findings by the *faculty* member. An additional goal is to promote the best interest of students and others whose work depends on *faculty* direction. The UR is an

institution of trust; *faculty* must respect this principle and conduct their affairs in ways that do not compromise the integrity of the University. In addition the University recognizes that even the perception that *faculty* have financial interests in the outcome of their research can call in to question the credibility and objectivity of this research.

Faculty members are to conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, the purposes of this policy are to inform *faculty* about situations that generate conflicts of interest, to provide mechanisms for *faculty* and the University to manage those conflicts of interest that arise, and to describe situations that are prohibited. Every *faculty* member has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, a *faculty* member should discuss the situation with his or her department chair and school *Dean* as required by this policy.

DISCUSSION AND DETAIL

1) PRESENCE ON CAMPUS/LIMITATIONS REGARDING OUTSIDE PROFESSIONAL ACTIVITIES

The University of Rochester confers the privilege and obligation to pursue teaching, research, scholarship, and clinical care (whichever are appropriate to the position held). Fulfillment of these obligations requires a commitment of expertise, time, and energy.

A full-time appointment confers an obligation for a *faculty* member to have a significant presence on campus to be accessible to students and staff, and to be available to interact with UR colleagues throughout the academic year, unless the department chair and school *Dean* both have granted specific prior approval for extended or frequent absences from campus. Even activities such as pro bono work or government service in the public interest should be managed so they do not take precedence over or conflict with a *faculty* member's commitment to the University.

Specific activities that require explicit prior written approval of the department chair and *Dean* include, but are not limited to, serving as a PI on behalf of another institution or entity; serving in a significant managerial role of a for-profit entity; and assuming a board position in a for-profit company in which he or she has a *significant financial interest*.

2) ANNUAL AND AD HOC REPORTS

Each school *Dean* is ultimately responsible for the reporting process (typically handled by the department chair), as well as review of ad hoc reports. Each school must have a plan for distribution, receipt, processing, review and retention of reporting forms. The *Dean* should use his or her discretion and knowledge of local conditions to set up a system that works well for the school. The *Conflict Of Interest Committee* may request, at any time, a review of those processes.

Regardless of the reporting requirements, an individual, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of

inappropriate behavior. (*Faculty* members are encouraged to ask for guidance from their department chair or *Dean* or the Provost's Office even in situations that are not covered by the reporting procedures in this policy.)

If a *faculty* member, for reasons of confidentiality, wishes to have his or her report reviewed by someone other than the chair(s) or *Dean*, that option must be made available. It is the responsibility of the *faculty* member to make those arrangements with the *Dean*. In such cases, the *Dean* may designate an appropriate individual as the reviewer. If the *Dean* and *faculty* member cannot agree on an appropriate designee, the Provost or Senior Vice President for Health Sciences will review the report. In all cases, the *Dean* is expected to keep the department chair(s) informed as appropriate.

A sample Conflict Reporting Form is attached to this document. Individual schools of the University may design their own forms, including more information but not less than that requested on the sample form. For *faculty* with appointments in more than one department or unit, copies of the reporting form should be provided to all relevant units as indicated on the disclosure form. Should any reported conflict require reporting to a federal sponsor, the Office of Research and Project Administration will report in accordance with federal regulations. (See University Guidance for Investigators on Federal Disclosure and Notification Requirements.)

a) Annual Disclosures

All *faculty* must complete the University's Conflict Reporting Form. *Faculty* who are not *investigators* are required to complete the General Conflict Reporting section of the form. *Investigators* must complete both the General Conflict Report and the Investigator Reporting sections of the form. All forms must be submitted to the department chair or supervisor by March 1 for the previous calendar year, or within 60 days of appointment. (A new *faculty* member submitting a form within 60 days of appointment must complete the Investigator Reporting section of the reporting form only, or indicate on the form that he or she does not meet the definition of *investigator* as defined by this policy. All personnel involved in the management, negotiation, or control of sponsored research or technology transfer [e.g., relevant staff of the Office of Research and Project Administration and the Offices of Technology Transfer] also must complete the Investigator Reporting section of the reporting form annually. These forms must be completed by March 1 and submitted to the relevant supervisor.)

If the annual reporting form reveals a potential conflict, it will be forwarded promptly to the relevant *Dean* and a conflict management plan will be required (see Guidance on Developing a Conflict Management Plan).

b) Ad hoc Reports

In addition to annual reporting, certain situations require ad hoc reporting. Prior to entering into University sponsored projects, University technology licensing arrangements, or procurement of materials or services where the relevant *faculty* member, student, post-doctoral fellow, resident, staff, (or *family member*) has a *significant financial interest*, that individual must submit to the relevant chair (or supervisor) and school *Dean* a complete written report of his or her current or pending *significant financial interest* with the outside entity, the

relationship of the proposed University activity to the entity, and a conflict management plan.

While the potentially conflicted individual is responsible for submitting the management plan, he or she may seek the assistance of the Offices of Technology Transfer and the Office of Research and Project Administration.

3) DECISION OF THE DEAN

The *Dean* may decide to eliminate, reduce, or manage any conflict. The *Dean* will send his or her decision, in writing, to the *faculty* member (or other relevant party), with a copy to the *Conflict Of Interest Committee* and, as appropriate, to the relevant department chairs. The written decision must include an explanation of the reasons for the decision. Potential conflicts that involve more than one school will require for resolution a single recommendation agreed to by all relevant *Deans*. If a *Dean's* decision conflicts with University policy, the decision must be reviewed by the COI committee, and forwarded to the provost for a final decision. The *Dean* is expected to avoid both institutional and personal conflicts of interest; if there is a perceived or real conflict with the *Dean* in either making a decision or approving a plan involving a conflict of interest, the *Dean* should forward the matter to the *Conflict of Interest Committee* for review, in which case the Provost will make the final decision.

If the *Dean* determines that there is a conflict that can be managed, he or she must approve a management plan before any arrangement goes forward. The *faculty* member or *investigator* is entitled to expect relatively prompt action. If the *Dean* needs additional information from the *faculty* member or *investigator*, he or she must request that information within one month of receipt of the management plan. In the event that the *Dean* has not reached a decision within 45 days after a conflict of interest management plan is submitted and the *faculty* member or *investigator* has provided all relevant information to the *Dean*, the requester may make an appeal using the general grievance procedure as described in the Faculty Handbook.

Before approving a management plan, the *Dean* should seek advice from the relevant department chair(s) if it is appropriate to do so. A *Dean* may also seek assistance from the *Conflict Of Interest Committee* or others knowledgeable in the field.

If time is of the essence, the *Dean* may approve an interim management plan and update the plan as more information becomes available.

If the *faculty* member or *investigator* believes that improper procedures have been applied or that bias or prejudice influenced the procedures in the decision of the *Dean* regarding a potential conflict of interest, the *faculty* member or *investigator* may make an appeal to the Provost through the general grievance procedure, or other appropriate grievance process as described in the Faculty Handbook.

A *Dean's* decision to impose sanctions on a *faculty* member because of failure to comply with this policy, or failure to comply with the decision of the *Dean* (or counterpart) or Provost, will be subject to the same process (including a written explanation of the decision to the *faculty* member, department chair(s), and *Conflict Of Interest Committee*, and the right of the *faculty* member

to appeal the decision in accordance with the grievance procedure as outlined in the Faculty Handbook.)

4) OTHER UNIVERSITY OFFICIALS ENCOUNTERING CONFLICTS

Senior administrators, including but not limited to the Directors of the Office of Technology Transfer, Office of Research and Project Administration, and the Research Subjects Review Board, also may seek the advice of the *Conflict Of Interest Committee* if a potential conflict has emerged in the course of exercising their University responsibilities.

5) MANAGEMENT OF CONFLICTS

To address complex situations, oversight committees may be established by each school *Dean* to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral scholars), and to ensure open and timely dissemination of the research results, etc.

6) CLINICAL TRIALS

Clinical trials involve particularly sensitive issues in those cases where the *investigator* has personal financial interests related to the *clinical trial*. *Faculty* members who have a *significant financial interest*, when conducting *clinical trials*, must report their *significant financial interest* in accordance with this policy as described in Section 2 and follow the ad hoc reporting/approval process in that Section. (This reporting requirement is in addition to any disclosures required by the University's IRB.) Note that any salary, royalties, or payments for service from, or equity ownership in, a company that affects, appears to affect, is affected by, or appears to be affected by, the research is considered to be a *significant financial interest* if the research involves human subjects. Salary and other payments from the University of Rochester are not included in the definition of *significant financial interest* (see pages 2-3 of this policy for the definition.)

An individual who holds a *significant financial interest* in *clinical trial* research may not conduct such research at the University unless he or she can show compelling reasons to do so. This prohibition extends to all who report (directly or indirectly) to the financially conflicted individual. The determination of whether or not there exist compelling circumstances for the financially conflicted individual to conduct the trial will be made by the *Dean* after examining the *investigator's* written justification, and seeking the advice of the department chair(s) as appropriate. In the event of compelling circumstances, an individual holding a *significant financial interest* in *clinical trials* research may be permitted to remain involved in the research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research (e.g., the phase of the *trial*). However, when the *significant financial interest* is an equity interest in a start-up company that licenses or manufactures the investigational product, participation in any manner other than a consulting role is prohibited.

If the *Dean* determines that the circumstances are compelling, a conflicted *faculty* member seeking involvement in a *clinical trial* must devise a written conflict management plan to be approved by the *Dean* in advance of initiating the *trial*. In all *clinical trials* with a conflicted *faculty* member, the

conflict management plan must include at a minimum, a full disclosure of the interest (to research subjects and others as appropriate, and in publications). In most circumstances, the management plan should also require that informed consent be obtained by a clinician with no financial ties to the research. The *Dean* may permit the conflicted *faculty* member to obtain consent only in situations where the financial interest is de minimus and no other qualified individual would be available to explain the risks, benefits and alternatives to participating in the trial. Further, the management plan should seek to identify another principal *investigator* to oversee the administration of the trial, including enrollment of subjects, the subject consent process, testing of the drug or device, and analysis of results. The appointed *investigator* must be qualified to administer the study protocol, and must not be someone over whom the conflicted *investigator* has supervision. A conflicted individual may, with the approval of the *Dean*, continue his or her involvement in the *clinical trial*, typically in a technical advisor role. Only when there is a critical need for the conflicted *investigator* to remain the principal *investigator* may the *Dean* approve such a role. A written management plan that allows for the conflicted *investigator* to be the PI must include a justification for this departure from standard protocol.

Before approving a management plan for a *clinical trial*, the *Dean* should seek advice from the relevant department chair(s) unless that individual also has a conflict of interest related to the trial. *Deans* also may bring proposed conflict management plans to the *Conflict of Interest Committee* for review and advice before they are agreed to by the relevant parties; however, they are not required to do so. The approved conflict management plan must be submitted to the *Conflict of Interest Committee* so that the Committee can review plans for consistency, and to the relevant department chair(s) as appropriate. The conflicted *investigator* must submit his or her approved conflict management plan to the IRB at the time the protocol is submitted for review.

7) APPROPRIATE USE OF UNIVERSITY RESOURCES, INCLUDING FACILITIES, PERSONNEL, EQUIPMENT, AND INFORMATION

Faculty may not use University resources, including facilities, personnel, equipment, *confidential information*, or the University's name, logo, servicemark, or trademarks, as part of their outside consulting activities or for any other non-University purposes. *Faculty* must report on a timely basis the creation or discovery of all potentially patentable inventions created or discovered as a result of substantial use of University resources. The following activities are prohibited:

- a) A *faculty* member involving those students whom he or she directly supervises or advises in a University graduate program in business activities outside of the University in which the *faculty* member has a *significant financial interest* and/or officer or director role, unless approved by the *Dean*. Before approval, the *Dean* should seek advice from the relevant department chair(s). If the *Dean* approves such involvement, the *faculty* advisor, student, and *Dean* must agree in writing to a conflict management plan. The plan must include, at a minimum: i) ongoing oversight by a faculty committee (e.g., the thesis committee), ii) a guarantee that financial support will not decline before completion of the degree requirements as long as the committee judges the student's progress to be acceptable, and iii) a guarantee that a suitable advisor will be appointed to replace the conflicted advisor if necessary;
- b) Assigning the *faculty* member's students, staff or postdoctoral scholars tasks within the University for purposes of potential or real financial gain of the *faculty* member rather than the advancement of the scholarly field or the students' educational needs;

- c) Granting access to UR resources or services for purposes outside the University's missions, or offering inappropriate favors to outside entities in an attempt to unduly influence them in their dealings with the University;
- d) Using for personal gain, or granting unauthorized access by others to, University *confidential information*; and
- e) Claiming ownership or assigning ownership to any third party of an invention resulting from research involving the use of University resources that are not generally available to the University community. Examples of University resources that are considered to be generally available include, but are not limited to, standard computers, widely-used software, telephones, and the library. A *Faculty* member who is uncertain about the application of this section should discuss his or her situation with the *Dean*. Ownership of computer software and copyrightable material may require special consideration. (Please refer to the University policy on Intellectual Property and Technology Transfer.)

8) RECORD RETENTION

The *Deans* will retain all reporting forms, conflict management plans, and related documents for a period of five years after the completion of the relevant research or five years after the conflict has ended, whichever is longer.

9) CONFIDENTIALITY

To the extent permitted by law, all reporting forms, conflict management plans, and related information will be confidential. However, such information will be made available to an agency funding research of the *faculty* member upon written request if permitted or otherwise required by law.

10) OTHER COMPLEMENTARY POLICIES

The following University of Rochester policies relate to this policy:

Policy on Intellectual Property and Technology Transfer

<http://www.rochester.edu/ott/?policies>

Policy on Institutional Conflict of Interest in Research Activities

<http://www.rochester.edu/ORPA/policies/COIresearch.pdf>

Conflict of Interest (Business Transactions)

<http://www.rochester.edu/working/hr/policies/pdfpolicies/113.pdf>

Purchasing Services Guidelines on Conflict of Interest

Federal Requirements Regarding Financial Disclosures and Agency Notifications

Policy History:

8/02 Adopted by the Provost's Conflict of Interest Committee

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1/04 Prologue amended by Provost's Conflict of Interest Committee

1/08 Amended by Provost's Conflict of Interest Committee