

**University of Rochester**



affiliated with institutions of higher education, and academic teaching hospitals and medical centers.

“Significant Financial Interest” means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not paid by the University of Rochester.

Deans may adopt lower financial thresholds for determining that a Financial Interest is a Significant Financial Interest for some or all categories of research conducted within their respective schools. They will submit such policies to the COI Committee for its review and information.

“Financial Conflict of Interest” means a Financial Interest or Significant Financial Interest that the University reasonably determines could directly and significantly affect

National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

**CONFLICT OF COMMITMENT:**

The University of Rochester confers upon faculty 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.

Conflicts of commitment are to be avoided because they violate the principle that faculty are paid by the University to fulfill their University commitments, detract from the educational and research process and may generate disputes between faculty and the Uevfxnge( c)6e d meav66cau

The goal of the policy is to avoid or to manage situations that call into question the credibility and objectivity of an investigator or the University's research and findings. An additional

must disclose their Significant Financial Interests to their supervisors annually, on a form or using the system adopted by the Director of ORPA or UR Ventures as applicable. These forms must be completed by March 1 and submitted to the relevant supervisor.

The Deans may require annual disclosure of all or a broader category of Financial Interests for their respective schools or units, even though such Financial Interests may not meet the definition of Significant Financial Interests.

**b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All faculty, and all non-faculty Investigators, must disclose their Significant Financial Interests to the University, through their Dean or the Dean's designee, within 30 days of their initial appointment or employment. Chairs and division chiefs are encouraged to discuss outside financial interests with faculty candidates during the recruitment process, so any actual or potential conflicts of interest can be discussed and addressed as appropriate.

Prior to entering into University sponsored projects, University technology licensing arrangements, or procurement of materials or services where the faculty member or non-faculty Investigator has a Significant Financial Interest, the faculty member or non-faculty Investigator must affirm that their last annual disclosure is complete and accurate, or submit an ad hoc updated disclosure of his or her Significant Financial Interest with the outside entity to ORPA, and, where appropriate, to UR Ventures or Corporate Purchasing. The University will not submit a research proposal unless the Investigator(s) have submitted such ad hoc COI disclosures.

In addition, all Investigators must submit to their Dean an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year, within thirty (30) days of discovering or

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## 2) REVIEW AND DECISION OF THE DEAN

If the disclosure form reveals a Significant Financial Interest, it must be reviewed by the Dean or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Dean must take action to eliminate, reduce or manage the conflict, as appropriate. Conflicts of interest that involve more than one school require a single management strategy agreed to by all relevant Deans.

For purposes of research, a Financial Conflict of Interest will exist when the Dean or designee determines that a Financial Interest or Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of University research. Deans may also decide to manage Financial Interests or Significant Financial Interests that are not Financial Conflicts of Interest, to promote transparency and avoid the appearance of conflicts of interest.

If the Dean determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing, submitting and signing a proposed management plan, in consultation with ORPA. Before approving a management plan, the Dean should consult with the relevant department chair(s) unless it is not appropriate to do so (e.g. if the chair has an institutional conflict of interest). All conflict of interest management plans approved by the Deans must be submitted to the COI Committee for its review and approval. Investigators are entitled to expect relatively prompt action. If time is of the essence, the Dean may approve an interim management plan and update the plan as more information becomes available.

The Dean is responsible for monitoring Investigator compliance with management plans. To address complex situations, oversight committees may be established by the Dean to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

The Dean may consult the COI Committee for guidance in interpreting this policy, adopting school-specific policies or guidelines, or in the application of the policy to particular situations. The Dean should consult the COI Committee prior to making any decision that directly conflicts with this policy.

Deans must avoid both institutional and individual conflicts of interest personally. If a Dean has an actual or apparent conflict in either making a decision or approving a plan involving a conflict of interest, the Dean should forward the matter to the COI Committee for review, and the Provost will make the final decision.

If the Investigator believes that improper procedures have been applied or that bias or prejudice influenced the procedures in the decision of the Dean regarding a conflict of

interest, the Investigator may appeal to the Provost through the general grievance procedure, or other appropriate grievance process as described in the Faculty Handbook.

### **3) OTHER UNIVERSITY OFFICIALS ENCOUNTERING CONFLICTS**

Senior administrators, including but not limited to the Directors of UR Ventures, Office of Research and Project Administration, and the Research Subjects Review Board, also may seek the advice of the COI Committee if they identify a potential conflict of interest in the course of exercising their University responsibilities.

### **4) CLINICAL TRIALS**

#### **a) Review of Financial Interests Related to Clinical Trials**

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial. Accordingly, all Financial Interests related to clinical trials that are disclosed to the Dean will be reviewed to determine whether they constitute Financial Conflicts of Interest.

#### **b) Transparency Policy for Clinical Trials**

In the interest of promoting transparency, whenever an Investigator has a Financial Interest related to a clinical trial, certain requirements will apply regardless of whether the Financial Interest constitute a Financial Conflict of Interest, as follows:

- i) The Investigator must disclose his or her Financial Interest in publications, presentations and press releases that involve the research related to the Financial Interest;
- ii) The Investigator must disclose his or her Financial Interest to the study coordinator who oversees the subject consent process, and any other individuals involved in obtaining informed consent, and any other study personnel or students involved in the study;
- iii) The subject consent form must include a disclosure approved by the RSRB; and
- iv) The Investigator must promptly notify the Dean or designee of any additional Financial Interests related to the research that he or she receives or expects to receive.

#### **c) Management of Financial Conflicts of Interests in Clinical Trials**

An Investigator who holds a Financial Conflict of Interest related to a clinical trial may not conduct such research at the University unless there are compelling reasons to do so, as determined by the Dean, or it otherwise fits within guidelines adopted by the Dean in consultation with the COI Committee. This prohibition extends to all who report (directly or indirectly) to the Investigator in question. The determination of whether or not there are compelling circumstances will be made by the Dean after reviewing the Investigator's written justification, and seeking the advice of the department chair(s) as appropriate. In the event of compelling circumstances, the





the decision of the Dean or Provost, will be described in a written explanation of the decision to the Investigator, department chair(s), COI Committee, and, where applicable, the Research Subjects Review Board, and will notify the individual of the right to appeal the decision in accordance with the grievance procedure as outlined in the Faculty Handbook or Human Resources policies, as applicable.

**b) Retrospective Review**

In addition, if the Dean determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Dean will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the at6 inct oae te at6 inct oae

is determined that the Investigator has not complied with this policy or with a management plan related to their activities. Deans may determine that training must be required for all Investigators and/or faculty in their respective schools, not only those engaging in research funded by the Public Health Service.

#### **9) 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 appointees 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 University 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.