

Adopted by University Conflicts of Interest Committee on September 26, 2005 (6.8.06)
Adopted by President Seligman on December 12, 2006

University of Rochester

Policy

Institutional Conflict of Interest in Research Activities

Scope of Policy

This policy provides rules concerning the decision-making processes of the University of Rochester as an institution in situations where the University may have (or be perceived to have) a conflict of interest relating to research conducted at the University.

The University, as an entity, may have a conflict of interest whenever the financial interests of the institution might affect – or reasonably appear to affect – institutional processes for the conduct, direction, review or oversight of research.

This policy does not concern potential conflicts of interest of individuals affiliated with the University. Conflicts of interest of individual faculty and staff members are covered in the following policies:

- Faculty Policy on Conflict of Commitment and Interest – Research Policy Handbook
- Policy on Intellectual Property and Technology Transfer
- Code of Conduct for Business Activities
- Personnel Policy 113 on Conflicts of Interest
- Personnel Policy 123 on Outside Employment
- Purchasing Policy on Conflict of Interest
- Strong Memorial Hospital Policy on Pharmaceutical Company Representatives
- Faculty Handbook Policy on External Activities Relating to Research and Scholarship and Conflict of Interest
- School of Medicine & Dentistry Conflict of Interest Policy for Clinical Trials(draft, not adopted)
- Research Subjects Review Board Policy regarding Conflict of Commitment and Interest
- SMD Faculty Handbook
- Board of Trustees Policy regarding Conflicts of Interest
- Medical Center Board Policy on Conflicts of Interest

Policy

The University, as an entity, may have an institutional conflict of interest related to research activities whenever the financial interests of the institution might directly or significantly affect – or reasonably appear directly and significantly to affect – institutional processes for the conduct, direction, review or oversight of research.

The University acts through the actions of people with administrative authority and responsibility. If an individual has significant administrative authority and responsibility over issues involving research, including decisions with respect to research contracting, allocation of resources, acceptance or monitoring of risk derived from research, an institutional conflict of interest will be deemed to exist if that individual has a personal financial conflict of interest, real or apparent, in a particular research project. (Significant administrative authority and responsibility means the type of authority normally exercised by an officer, dean, department chair, division chief in a clinical department or center director.)

The University will seek to eliminate or manage any institutional conflicts of interest related to research activities. The University will disclose in an appropriate manner and form to the relevant concerned audiences all institutional conflicts of interest related to research activities.

If human subject research is involved, the University will take particular care with respect to management of any potential institutional conflict of interest to assure that the welfare of human subjects and the integrity of the research is not compromised.

The University will separate the functions and administrative responsibilities related to research from those related to investment of institutional endowment and other financial funds and to institutional purchasing.

Decisions with respect to investment of institutional endowment and other financial funds are delegated by the Board of Trustees of the University to its Investment Committee and overseen by the Senior Vice President for Institutional Resources and the other staff of the Investment Office. Individual investment decisions are delegated to and made by outside investment advisors or managers. The criteria that govern the making of such investment decisions specifically shall preclude consideration of information related to the University's research activities. University investments in lieu of taking royalties and/or in start-up companies related to University research are institutional financial interests covered by this Policy.

If any person affiliated with the University (defined to include faculty, staff, researcher, administrator, student, or volunteer) believes that the University as an institution may have a conflict of interest, which is not being addressed, with respect to the conduct,

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direction, review or oversight of research, he or she should immediately inform the Provost of the University about the situation.

Process

If the Provost determines that a significant possibility exists that there is an institutional conflict with respect to research, the Provost will notify the people involved to refrain from making a decision or taking any action until the situation can be investigated and a decision made as to whether a conflict exists and, if it does, the plan for alleviating or managing the conflict put in place.

The Provost will convene the University Conflict of Interest Committee to consider the facts concerning any potential institutional conflict with research and ask it to investigate the situation and determine if a real or apparent conflict exists and, if one does, to make a recommendation for the conflict's management, reduction or elimination (known as an institutional management plan.) The final decision with respect to the handling of an institutional conflict of interest will be made by the President after receiving the recommendations of the Conflict of Interest Committee and the Provost.

For purposes of such investigations/determinations, the Provost can appoint additional ad hoc members, including people not affiliated with the University, to the Conflict of Interest Committee in order to assure appropriate consideration of the conflict. Likewise, the Provost can require some or all of the standing members of the Conflict of Interest Committee to recuse themselves if so doing would better assure the integrity of the process of considering the alleged institutional conflict.

If the allegations of conflict involve the actions or financial interest of the Provost, the President will assume the role designated for the Provost in the foregoing process.

Special Considerations for Clinical Trials

If human subject research is involved, the University will take particular care with respect to management of any potential institutional conflict of interest to assure that the welfare of human subjects and the integrity of the research is not compromised.

If an institutional conflict of interest exists regarding any clinical trial, the University will only lead, direct or control a Phase I or Phase II study if compelling scientific reasons exist and an institutional conflict of interest management plan is in place. If an institutional conflict of interest exists regarding any clinical trial, the University generally will not lead, direct or control (e.g. be the lead site or serve on the Executive Committee of the study) a Phase III or Phase IV clinical trial except in extraordinary circumstance where not to do so would seriously jeopardize the science and the potential public

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benefits and then only if an institutional conflict of interest management plan is in place
If an institutional conflict of interest exists regarding any clinical trial, the University may participate in any phase clinical trial solely as a study site if another institution(s) leads, directs and controls the study and an institutional management plan is in place.

Factors to be considered in determining whether compelling reasons exist for continued University involvement include, but are not limited to:

- Whether the trial is at multiple sites and, if so, whether the University's role is relatively passive or is the site gathering and/or monitoring the data from all other sites.
- Whether the University's resources are fundamentally important to the progress of the science or the University investigator is uniquely qualified or necessary to administer the trial.
- Whether the interests of the human subjects will be adversely affected by use or non-use of the University as a site.
- The proportion of the total subjects in the study that are under the supervision of the University.

If the decision is made to conduct the study at the University when an institutional conflict of interest exists, the Provost will appoint a monitoring committee to formulate, adopt and oversee compliance with an institutional conflict of interest management plan to protect human subjects and the integrity of the research of the clinical trial from any influence from the Institutional conflict. The institutional conflict of interest management plan must be shared with the University's Office of Human Subjects Protection and must include a requirement of full disclosure of the University's interest to research subjects and, if appropriate, to others. In a clinical trial involving human subjects where the University is deemed to have a real or perceived conflict, the management of the conflict by the monitoring committee also will include monitoring of any related individual faculty or investigator conflict management plans. The monitoring committee must be chaired by a respected scientist from outside the University community who has no real or apparent conflict of interest in the study.

Potential Sources of Institutional Conflicts of Interest

A financial interest in a commercial entity owned by the University, in and of itself, does not automatically present a conflict of interest. There are various potential sources of institutional conflict of interest, including, but not limited to:

- 1) University ownership of equity interests, other corporate securities or entitlements in entities that sponsor research at the University that are obtained through technology transfer or transactions with such entities other than through decisions made by disinterested outside investment advisors who have been instructed not to take University research activities into consideration in their decision-making.

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- 2) University receipt of royalties (or potential royalties) that depend upon future sale of products or technology related to University ongoing research or other consideration from sale of products or technology related to University ongoing research.
- 3) University receipt of substantial or reoccurring gifts, equipment donations or promises thereof (direct or implied) that are not a part of a disclosed sponsorship or sponsored program from commercial sponsors of research if there is an actual or implied quid pro quo owed to the donor that relates to, or could give the appearance of relating to, the research.

Examples

The following are examples of institutional financial interests that may affect – or reasonably appear to affect – institutional processes for the conduct, direction, review, or oversight of research and, therefore, constitute potential conflicts of interest:

- A company proposes to provide research funding to the University for further development of a technology previously licensed by the University to the company and from which company a University's financial interest is derived (e.g., a royalty stream).
- A company in which the University has a significant equity interest (not acquired, held and controlled by an outside investment manager precluded from considering information related to the University's research activities) proposes to provide funding for research of any kind, whether or not the proposed research or clinical trial is related to the technology that was previously licensed to the company and from which the equity is derived.
- A company proposes to provide funding for a clinical trial of a product or device that was developed by the company with the use of University-owned technology previously licensed to the company and from which University financial interest is derived.

Application to Current Research

The applicability of the Policy to research underway at the time this Policy is adopted will be considered on a case by case basis by the Provost and the University Conflict of Interest Committee.