

**INTRODUCTION FOR THE URMC GUIDELINES  
FOR MANAGING FACULTY FINANCIAL CONFLICTS  
OF INTEREST IN CLINICAL TRIALS**

The attached table entitled “Guidelines for Managing Faculty Financial Conflict of Interest: Clinical Trials” is to be used as a supplement to existing University and URMC policies on Conflicts of Interest. University policy dictates that an actual or potential financial conflict of interest in a clinical trial, which arises when a faculty member involved with the clinical trial holds a significant financial interest in the research being conducted, must be disclosed by the faculty member and managed or eliminated, as appropriate. If URMC determines that a conflict can be managed, a management plan must be developed by the faculty member and approved by the Dean of the School of Medicine and Dentistry.

These guidelines highlight that managing actual and potential financial conflict of interest depends on two factors: the degree of the financial interest and one’s role in the clinical trial. The table should be used to assist faculty and staff regarding the actions required, including the need for a Conflict of Interest Management Plan and whether that plan will require divestment of the conflict or recusal from study activities. An independent assessment of one’s potential or actual conflict should be made for each clinical trial, which may result in the need for more than one plan for the faculty member in question.

12/05

## URMC Guidelines for Managing Faculty Financial Conflict of Interest: Clinical Trials

Increasing Financial Interest <span style="float: right;">→</span>		
<div style="display: flex; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold; margin-right: 5px;">Increasing Responsibility in Clinical Trial</div> <div style="font-size: 2em; margin-right: 5px;">↑</div> </div>	<p>Involved with study planning, data analysis, data interpretation, or critical writing/editing of manuscript such that authorship is expected. (e.g., principal investigator, steering committee member, biostatistician)</p>	<p>If personal income<sup>*</sup>, equity interest<sup>**</sup>, and gifts combined are or are expected to be valued at <b><u>less than or equal to \$10,000</u></b> annually during the project period<sup>***</sup></p> <p style="text-align: center;">Or</p> <p>If indirect income<sup>****</sup> is or is expected to be valued at <b><u>less than or equal to \$15,000</u></b> annually during the project period</p> <p style="text-align: center;">Or</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and</p> <ul style="list-style-type: none"> <li>• Not yet approved drug, device or procedure and pilot study to inform pivotal clinical trial</li> </ul>
	<p>Overseeing local or central coordination study activities, consenting subjects, limited or no review of manuscript such that authorship is <b>not</b> expected. (e.g., site principal investigator, study coordinator, programmers, information analysts)</p> <p>Technical operator (e.g., surgeon, procedural specialist) in an unblinded study whose actions directly impact study outcomes</p>	<p>If personal and indirect income, equity interest, and gifts combined are or are expected to be valued at <b><u>less than or equal to \$25,000</u></b> annually during the project period</p> <p style="text-align: center;">Or</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and</p> <ul style="list-style-type: none"> <li>• Not yet approved drug, device or procedure and pilot study to inform pivotal clinical trial</li> </ul>
<b>ACTION REQUIRED</b> →	<b>Disclosure and Conflict of Interest Management Plan</b> †	<b>Plan must include Divestment or Recusal</b> ††
<p>For the following trial-related activities (and the presence of <u>any</u> potential financial conflict), <b>Disclosure and a Conflict of Interest Management Plan</b>† <b>are necessary</b>. There is <u>no need</u> to divest or recuse.</p> <ul style="list-style-type: none"> <li>▪ Blinded rater measuring outcomes</li> <li>▪ "On-call" investigators responding to emergent subject adverse events</li> <li>▪ Administrative PI of departmental research division coordinating clinical trials, but with no direct study responsibility</li> </ul>		

†For faculty in supervisory roles who may have mentoring or educational influence over others, the plan should include steps to manage mentoring/educational conflicts as well as research conflicts.

††When one decides to retain the financial interest but recuse oneself, a “recusement” management plan is required to assure 1) that the financially conflicted faculty has no real or perceived influence over those conducting the study and 2) that those conducting the study have free and unrestricted right to analyze, interpret and publish the data.

\* Personal income is in addition to University salary. The income can be from any organization or company that could benefit, appear to benefit, is benefited by, or appears to be benefited by the research activities or the results of the research.

\*\* Equity interest includes all stock options. Pre-IPO stock offerings are valued in present dollar terms and should be less than 5% of the total outstanding equity.

\*\*\* Defined as one month after the publication of the MAIN study results in a peer-reviewed journal.

\*\*\*\* Indirect income includes payment received and directed to the URMC in which the donation could or could appear to benefit the faculty member. This includes a University of Rochester discretionary account.