### URMC Guidelines for Managing Faculty Financial Interests in Clinical Trials

**NOTE:** A financial interest is a **FINANCIAL CONFLICT OF INTEREST** only if the interest **DIRECTLY AND SIGNIFICANTLY AFFECTS THE DESIGN, CONDUCT OR REPORTING OF THE RESEARCH**

<table>
<thead>
<tr>
<th>Type of Interest and Considerations</th>
<th>Requires the following</th>
<th>Management Plan</th>
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<tbody>
<tr>
<td><strong>Financial Interest that is not a Conflict of Interest, but may be perceived as a COI</strong></td>
<td><strong>0 to $5,000 – Financial Interest</strong>&lt;br&gt;• Any role in the study</td>
<td><strong>Transparency Policy applies:</strong>&lt;br&gt;• Disclosure in publications, presentations, press releases&lt;br&gt;• Disclosure to study personnel&lt;br&gt;• Disclosure in the consent form</td>
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<td><strong>Significant Financial Interest that is not a Financial Conflict of Interest</strong>&lt;br&gt;Factors that weigh against finding of fCOI:</td>
<td><strong>At a minimum, Transparency Policy applies:</strong>&lt;br&gt;• Disclosure in publications, presentations, press releases&lt;br&gt;• Disclosure to study personnel&lt;br&gt;• Disclosure in the consent form</td>
<td><strong>Financial interest must remain ≤$25,000; additional management strategies may be recommended as appropriate for the purposes of mitigating a perceived financial conflict of interest, e.g., the individual may not obtain consent or oversee staff; and/or a lower cap on external compensation may be imposed</strong></td>
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<td>• Lack of, or minimal role of the individual in the study planning,&lt;br&gt;• Lower risk to study subjects&lt;br&gt;• Smaller amount of interest (≤$10,000)*&lt;br&gt;• Lack of, or minimal contribution to the results (data analysis/interpretation, writing/editing of manuscripts)&lt;br&gt;• Single site of multi-center (not overseeing)</td>
<td><strong>Must divest or reduce the financial interest to ≤$25,000, if higher</strong></td>
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<td><strong>Significant Financial Interest that is Determined to be a Financial Conflict of Interest</strong>&lt;br&gt;Factors that weigh toward finding of fCOI:</td>
<td><strong>Compelling Reason for the Individual to serve as an Investigator, based on analysis of:</strong>&lt;br&gt;• nature of the science;&lt;br&gt;• nature of the interest and how closely related to the research;&lt;br&gt;• how the research could be affected by the interest (e.g., phase of the study)</td>
<td><strong>Management Plan requires:</strong>&lt;br&gt;• Disclosure in publications, presentations, press releases&lt;br&gt;• Disclosure to study personnel&lt;br&gt;• Disclosure in the consent form&lt;br&gt;• Financial interest must remain ≤$10,000&lt;br&gt;Additional management strategies may be imposed, e.g., the individual may not obtain consent or oversee staff; and/or a lower cap on external compensation may be imposed</td>
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<td>• Significant role in the study (study planning, writing protocol),&lt;br&gt;• Higher risk to study subjects&lt;br&gt;• Greater amount of interest (&gt; $10,000)*&lt;br&gt;• Significant contribution to the results (data analysis/interpretation, writing/editing of manuscripts)&lt;br&gt;• Single center or oversight of multi-center</td>
<td><strong>Must divest or reduce the financial interest to ≤$10,000, if higher</strong></td>
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<tr>
<td><strong>Financial Conflict of Interest – equity in a start-up company that licenses or manufactures the investigational product</strong></td>
<td><strong>The individual’s participation limited to consulting</strong></td>
<td><strong>Individual must divest interest to conduct the trial or only participate as a consultant</strong></td>
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</table>

*Note: the amounts indicated with an * are guidelines and not absolute thresholds.*

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Important Definitions

Financial Interest - monetary value received or held by a faculty member, non-faculty Investigator or such an individual’s family member, whether or not the value is readily ascertainable, including, but not limited to:
- Compensation or other payments for services (e.g., consulting fees, honoraria, or paid authorships other than scholarly works);
- Any equity interests (e.g., stocks, stock options or other ownership interests);
- Intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Significant Financial Interest - a financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:
- Compensation/Payment greater than $5,000 in the year
- Equity
  - Publicly traded greater than $5,000
  - Non-publicly greater than $0
- Intellectual property rights and interests of any value, that is NOT paid by the UR

Financial Conflict of Interest - a financial Interest or significant financial interest that the University reasonably determines could directly and significantly affect the design, conduct or reporting of University research

Investigator- any individual who is responsible for the administration, design, conduct, or reporting of sponsored research, internally funded research that involves human subjects, or proposals for such funding (e.g. PI, co-PI, Sub-I, postdoctoral associates, senior scientists, graduate students, study coordinators) Note: postdoctoral associates or graduate students will normally not be independently responsible for the design, conduct or reporting.

Institutional Responsibilities - responsibilities associated with an Investigator’s University appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service

Clinical Trial - all research studies that involve interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

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