

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

Type of Interest and Considerations		Requires the following	Management Plan
Financial Interest that is not a Conflict of Interest, but may be Perceived as a COI	0 to \$5,000 – Financial Interest <ul style="list-style-type: none"> Any role in the study 	Transparency Policy applies: <ul style="list-style-type: none"> Disclosure in publications, presentations, press releases Disclosure to study personnel Disclosure in the consent form 	No management plan required Note: Must remain ≤\$5,000 or further review required
	Significant Financial Interest that is not a Financial Conflict of Interest Factors that weigh against finding of fCOI: <ul style="list-style-type: none"> Lack of, or minimal role of the individual in the study planning, Lower risk to study subjects Smaller amount of interest (≤\$10,000)* Lack of, or minimal contribution to the results (data analysis/interpretation, writing/editing of manuscripts) Single site of multi-center (not overseeing) 	At a minimum, Transparency Policy applies: <ul style="list-style-type: none"> Disclosure in publications, presentations, press releases Disclosure to study personnel Disclosure in the consent form Must divest or reduce the financial interest to ≤\$25,000, if higher	Financial interest must remain ≤\$25,000; additional management strategies <u>may</u> 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
Financial Conflict of Interest	Significant Financial Interest that is Determined to be a Financial Conflict of Interest Factors that weigh toward finding of fCOI: <ul style="list-style-type: none"> Significant role in the study (study planning, writing protocol), Higher risk to study subjects Greater amount of interest (>\$10,000)* Significant contribution to the results (data analysis/interpretation, writing/editing of manuscripts) Single center or oversight of multi-center 	Compelling Reason for the Individual to serve as an Investigator, based on analysis of: <ul style="list-style-type: none"> nature of the science; nature of the interest and how closely related to the research; how the research could be affected by the interest (e.g., phase of the study) Must divest or reduce the financial interest to ≤\$10,000, if higher	Management Plan requires: <ul style="list-style-type: none"> Disclosure in publications, presentations, press releases Disclosure to study personnel Disclosure in the consent form Financial interest must remain ≤\$10,000 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
	Financial Conflict of Interest – equity in a start-up company that licenses or manufactures the investigational product	The individual’s participation limited to consulting	Individual must divest interest to conduct the trial or only participate as a consultant

*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.