POLICY

1. Purpose

Ensure that Investigator financial interests and financial conflicts of interest are appropriately identified through the IRB review system, and that financial conflicts of interest are managed or eliminated according to the University *Policy on Faculty Conflict of Commitment and Interest* to ensure there is no adverse effect on the protection of subjects, the integrity of the research, or the credibility of the Human Research Protection Program.

2. Scope

This policy applies to the University of Rochester Human Research Protection Program, with respect to Investigators responsible for the design, conduct, or reporting of human subject research at the University of Rochester as well as their immediate family members (i.e., dependents, spouses, and domestic partners).

3. Definitions

3.1. *Conflict of Interest* – A set of conditions in which an Investigator has a secondary interest (e.g. personal or financial gain) that may bias their judgment concerning their primary research interest (e.g., subject welfare, integrity of research). A financial conflict of interest exists when the University reasonably determines that a financial interest or a significant financial interest could directly and significantly affect the design, conduct or reporting of University research.

3.2. *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. This term also includes study coordinators, and may also include other individuals as determined by the Dean.

3.3. *Relying IRB* – The IRB that delegates the responsibility of IRB review and approval to another IRB.

3.4. *Reviewing IRB* – The IRB designated to review and approve human subject research as per 45 CFR 46.111 and in accordance with the Reliance Agreement.

4. References

4.1. FDA 21 CFR 54

4.2. University Policy on Faculty Conflict of Commitment and Interest (December 2015), which incorporates the requirements under HHS 42 CFR 50, Subpart F and HHS 45 CFR 94;
University Guidelines on Research Integrity and Conflict of Interest: Graduate Students and Postdoctoral Appointees (Revised May 2011);

URMC Guidelines for Managing Faculty Financial Interests in Clinical Trials (Revised December 2013)

4.3. Policy 504 IRB Reliance and Collaborative Research

5. Responsibilities

5.1. Investigators should conduct their institutional research responsibilities so as to avoid or minimize conflicts of interest.

5.2. Investigators are responsible for reporting their outside financial interests, and those of their immediate family members, to the University as required by the University of Rochester *Policy on Faculty Conflict of Commitment and Interest*, the applicable reporting requirements under FDA 21 CFR 54, and the guidelines referenced under Section 4.2 above, as applicable.

5.3. Investigators are responsible for reporting their outside financial interests, and those of their immediate family members, to the RSRB as part of the application in the IRB Review System, including any University required management strategies (i.e. transparency policy, management plans), as applicable.

5.4. When the RSRB is the Reviewing IRB, the RSRB is responsible for reviewing all management plans including any strategies put in place by the unaffiliated University.

5.5. When the RSRB is the Relying IRB, the RSRB is responsible for providing Conflict of Interest Management Plans including any management strategies to the Reviewing IRB, as applicable, in accordance with *Policy 504 IRB Reliance and Collaborative Research*.

6. Requirements

6.1. Investigators are required to disclose all conflicts including management plans/transparency checklists identified by the University to the RSRB at the time of an initial protocol submission, or to submit a modification to an existing study when a new conflict is identified and managed during the conduct of an active study.

6.1.1. The University will notify the RSRB of Investigator financial conflicts of interest via a copy of the final conflict of interest management plan or completed transparency policy.

6.2. When the RSRB is the Reviewing IRB, the RSRB will review the information included in the management plan or transparency policy to determine that the conflict has been adequately managed and that all management strategies are addressed in the study protocol and consent prior to RSRB approval (or in the case of an active study, continued approval).

6.2.1. During the review process, the RSRB will defer any financial interest not previously reported to the Conflict of Interest Advisory Committee to confirm whether the Dean has determined if there is a conflict of interest that must be eliminated or managed for the purpose of the University. This confirmation will be received by the RSRB before the study may be approved.

6.2.2. During the review process, the RSRB has the authority to request additional management strategies in addition to those already required by the University.

6.2.3. If the RSRB requests additional management strategies, it will advise the Chair of the SMD Conflict of Interest Advisory Group (CIAG), or the Chair's designee.

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Appendices:

None

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