

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection		Effective Date: 11/28/2022
	Institutional Conflict of Interest		Policy 104
		Version: 1.3	

POLICY

1. Purpose

Ensure any institutional conflicts of interest are appropriately identified through the RSRB online review system, and managed or eliminated according to the *University of Rochester Policy on Institutional Conflict of Interest in Research Activities* to ensure there is no inconsistency with or adverse impact on institutional processes for the conduct, direction, review or oversight of human subject research, as well as 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 (UR HRPP), with respect to research activities conducted at the University of Rochester.

3. Definitions

3.1. *Institutional Conflict of Interest* – A situation where the financial interests of the University might directly or significantly affect institutional processes for the conduct, direction, review or oversight of research. This may apply through the institution having a financial interest or through an institutional leader having a financial interest.

3.2. *Institutional Leader* – An individual who has significant administrative authority and responsibility over issues involving research (i.e., the type of authority normally exercised by an officer, dean, department chair, division chief in a clinical department, or center director).

4. References

- 4.1. FDA 21 CFR 54;
- 4.2. [University of Rochester Policy on Institutional Conflict of Interest in Research Activities](#);
- 4.3. [University of Rochester Policy – Faculty Conflict of Commitment and Interest](#), which incorporates the requirements under HHS 42 CFR 50, Subpart F and HHS 45 CFR 94;
- 4.4. [University of Rochester Conflict of Interest Committee Charter](#);
- 4.5. [Policy 504 IRB Reliance and Collaborative Research](#)

5. Responsibilities

5.1. The University is responsible for identifying institutional conflicts of interest (e.g., equity interests, royalties, financial interests of the University or its institutional leaders), and is responsible for managing, reducing or eliminating these conflicts in accordance with the *University Policy on Institutional Conflict of Interest in Research*.

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- 5.2. Institutional leaders are responsible for reporting financial interests in accordance with the University’s *Policy on Faculty Conflict of Commitment and Interest* and applicable reporting requirements under FDA 21 CFR 54.
- 5.3. When the RSRB is the Reviewing IRB, the RSRB is responsible for reviewing all management strategies put in place by the University.
- 5.4. When the RSRB is the Relying IRB, the RSRB is responsible for forwarding information regarding the management plan to the Reviewing IRB, as applicable, in accordance with *Policy 504 IRB Reliance and Collaborative Research*.

6. Requirements

- 6.1. The COI Committee will notify the RSRB of institutional conflicts of interest pertaining to research activities via a copy of the final institutional conflict of interest management plan.
- 6.2. When the RSRB is the Reviewing IRB, the RSRB will review the information included in the management plan to determine that the conflict has been adequately managed and that all management strategies are addressed in the study application and consent form, when applicable, prior to RSRB approval (or in the case of an active study, continued approval).
 - 6.2.1. During the review process, the RSRB has the authority to request additional management strategies in addition to those already required by the University.
 - 6.2.2. If the RSRB requests additional management strategies, it will advise the COI Committee.

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Appendices:

None



Revision History:

09/2016: Add reference to Policy 504, add sect 5.4, add hyperlinks, editorial changes
 02/2019: Change of IO and removal of T. Gommel as signatory; editorial changes
 11/2022: Administrative update section 4; Change IO, and editorial changes

Supersedes Date:

02/13/2019



Approved By:

DocuSigned by:

 Signer Name: Stephen Dewhurst
 Signing Reason: I approve this document
 Signing Time: 12/7/2022 | 4:21:09 PM EST
 E217A323058C451895F16072D41E27E0

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12/7/2022 | 4:21:16 PM EST

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 Signer Name: Kelley O'Donoghue
 Signing Reason: I have reviewed this document
 Signing Time: 12/7/2022 | 6:20:52 PM EST
 01BA85BD9A444F09983AC84603B8E36E

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12/7/2022 | 6:20:59 PM EST

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