O RUSH	Policy Title: RA-IRB-103 Disc Conflicts of Interest by IRB N	Policy Number:	
Document Owner: John Cobb		Approver(s): John Cobb	
Date Created: Not Set	Date Approved: 06/23/2021	Date Updated: 06/11/2021	Review Due: 06/23/2024
Applies To: RUMC □ RU □	RUMG □ ROPH □ R	RCMC □ RCH □ ROP	PG □ RCMG □

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Rush University Medical Center Policies and Procedures

Policy Number: RA-IRB-103

Category Name: Research

Title: Disclosure and Management of Conflicts of Interest by IRB

Members

Type: Policy and Procedure

Revision Date 12/2019 (replaces 2/2014 version)

Applies To: Rush IRB Members and IRB Administrative Staff

Policy Rush Institutional Review Board (IRB) members must

disclose all financial or other types of conflicts of interest in research, whether potential or actual, to the Rush IRB in accordance with Federal regulations and

Rush policies and procedures.

Procedure: For purposes of IRB deliberations, a "conflict of interest"

exists when an IRB member (a) is directly (as an investigator

or co-investigator) involved with the protocol under consideration, (b) has any personal stake (financial or otherwise) in the protocol or with the protocol's Sponsor, (c) has an immediate family member (spouse or independent children) involved in the design, conduct, or reporting of the

research, (d) has an immediate family member with a

personal stake (financial or otherwise) in the protocol or with the protocol's Sponsor, or (e) feels he or she cannot be totally objective about the review due to religious or other beliefs or collegial or social ties with one or more of the investigators. The IRB follows the guidelines set forth in Rush University Medical Center's Policy OP-0359 and CC-RC-008 regarding parameters of which conflicts must be

reported.

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Each IRB member will be required to complete the "Conflict of Interest in Research for IRB Members" form at the time of their tri-annual evaluation. The completed forms will be shared with the Director of Human Subjects Protection and be retained in the members' files in the Research and Clinical Trials Administration Office. IRB Members who are also Investigators will be required to satisfy requirements for disclosure and management of potential or actual conflicts of interest for Investigators at Rush set forth in Rush University Medical Center's Policy OP-0359 and CC-RC-008.

When an IRB member designated to conduct an expedited or exempt review has an actual or potential conflict of interest with an item assigned to them for review, they must disclose such conflict to the IRB Administrative staff. The IRB Administrative staff will then reassign the review to another IRB member designated by the IRB Chair to do such reviews.

In situations where an IRB member identifies a potential conflict of interest with an agenda item scheduled for review by the full IRB committee, he or she should inform the IRB Chairperson or IRB Administrative staff in advance of the meeting, whenever possible. At the convened meeting, the member may disclose a potential conflict of interest orally. The IRB Chairperson and committee will then discuss the specifics of the conflict and determine whether or not to recuse the member.

Any IRB member with a conflict of interest will only be present to provide information requested by the IRB and will be absent from the meeting room during the discussion and voting phases of the review and approval processes. The member will not count toward quorum during the review of the agenda item with which a conflict exists. The IRB minutes will reflect that these requirements were met.

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Reference 45 CFR 46.107(d)

21 CFR 56.107(e)

Rush University Medical Center Policy OP-0359
Rush University Medical Center Policy CC-RC-008

Related Forms IRB Member Conflict Of Interest Disclosure Agreement

Last Reviewed: 7/2020

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