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	10/2010 (replaces 6/2009 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 financial stake (direct or indirect) in the protocol or with the protocol's Sponsor, or (c) 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 regarding parameters of which conflicts must be reported.

Each IRB member will be required to complete the "Conflict of Interest in Research for IRB Members" form annually. 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.

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.

Reference	45CFR46.107(e) 21CFR56.107(e) Rush University Medical Center Policy OP-0359
Related Forms	IRB Member Conflict Of Interest Disclosure Agreement

Last Reviewed: 12/23/2011