

Rush University Medical Center Policies and Procedures

Policy Number: RA-IRB-109

Category Name: Research

Title: Institutional Review Board (IRB) Authority to Impose Study Restrictions

Type: Policy & Procedure

Revised: 2/2014 (replaces 7/2009 version)

Applies To: Rush Investigators/Study Staff, Rush IRB Members, and IRB Administrative Staff.

Policy **The Rush IRB has the authority to impose study restrictions at any point during the review process. Such restrictions may affect enrollment, investigator role or activities, and/or a determination that the study requires more frequent review than the standard annual process should the IRB so determine.**

Procedure: The Rush IRB may use the following criteria to determine whether study restrictions should be imposed:

- a) The study involves high risk to human subjects;
- b) The study involves vulnerable populations;
- c) The study involves large numbers of subjects;
- d) The IRB has concerns about safety due to DSMB reports received;
- e) The investigator has not complied with federal regulations or institutional policy or the investigator has previous instances of non-compliance;
- f) The IRB has concerns about the manner in which the study will be or is being conducted.

Requests for imposition of study restrictions will be documented in detail in the IRB meeting minutes, and include the type of and reasons for the restrictions.

Reference 45 CFR 46.103 (b)(4)(ii), 21 CFR 56.108(a)(2)

Last Reviewed: 4/8/2014