

March 18, 2016

Re: Ann & Robert H. Lurie Children's Hospital of Chicago Institutional Review Board  
Registration and Federalwide Assurance  
FWA #00001011 – Expires November 24, 2020  
IORG #0000368– Expires March 8, 2019

IRB Panel 1: #00000624  
IRB Panel 2: #00009723

To Whom It May Concern:

The Ann & Robert H. Lurie Children's Institutional Review Board (IRB) is duly constituted to conform with all federal regulation requirements of the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections, (OHRP) of the U. S. Department of Health and Human Services that govern research involving human subjects. No member of the IRB may participate in the IRB's review, or vote on any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The Lurie Children's IRB has written procedures for initial and continuing review of projects, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. The Lurie Children's IRB in its assurance assures that it meets all the requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) as well as 21CFR50 and 21CFR56 for all research involving human subjects.

Questions regarding the IRB and its federal assurances may be directed to my attention.

Sincerely,



Catherine A. Powers, MBA, CCRC, CIP  
Director, Office of Research Integrity and Compliance  
Children's Hospital of Chicago Research Center  
773.755.7489

