



**Statement of Compliance**

To Whom It May Concern:

In addition to the Department of Health and Human Services (DHHS) Federalwide Assurance of Compliance number FWA00003937 (compliance with 45 CFR 46), the University Hospitals Cleveland Medical Center (UHCMC) Institutional Review Boards (IRB) for Human Investigation (registration numbers IRB00000684, IRB00001691 and IRB00008600) adhere to the U.S. Food and Drug Administration (FDA) regulations promulgated under 21 CFR 50, 56, 312, 812. Investigators will receive formal certification of IRB review under these regulations upon IRB approval of the research project.

The UHCMC IRB is duly constituted, fulfilling all the requirements for diversity, and has written procedures for initial and continuing review for all human research protocols.

In addition the UHCMC IRB complies with the guidelines established under Good Clinical Practices (GCP) and the International Conference on Harmonization (ICH) to the extent required by the U.S. Food and Drug Administration.

A handwritten signature in blue ink, appearing to read 'a38', is positioned above the typed name of the signatory.

Grace A McComsey, MD, FIDSA  
Associate Chief Scientific Officer, University Hospitals Health System  
Director, UH Clinical Research Center  
Director, Dahms Clinical Research Unit  
John Kennell Endowed Chair  
Chief, Pediatric Infectious Diseases and Rheumatology  
Professor of Pediatrics and Medicine  
Case Western Reserve University