

Marva Moxey-Mims, MD KUH Deputy Director for Clinical Research Director, Pediatric Nephrology and Renal Centers Programs NIH, NIDDK, DKUHD 6707 Democracy Blvd. 2 Democracy Plaza, Room 639 Bethesda, MD 20892

Dear Dr. Mims:

Thank you for submitting a summary of the adverse events associated with the Chronic Kidney Disease in Children Study. We believe that the risks for this study have not changed during the study and that the study continues to be safe and well conducted.

Specifically, out of 1,141 glomerular filtration studies using iohexol infusions, there were 12 potential adverse events. All of these occurred in the very first two visits of the study. Adverse events included increased pulse, rash, nausea and vomiting. Two patients had decreased systolic blood pressure and three had elevated blood pressure. None of the events resulted in patient harm.

This important study continues to be a safe and important initiative. Please let me know if you have any questions.

Sincerely,

F. Bruder Stapleton, M.D.

Chairman, External Advisory Committee Chronic Kidney Disease in Children Study

Professor and Chair, Department of Pediatrics

Ford/Morgan Endowed Chair in Pediatrics

Associate Dean, University of Washington School of Medicine

Chief Academic Officer and Senior Vice President

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