



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

December 6, 2013

Dr. Susan Furth
Division Chief, Pediatric Nephrology
Laffey-Connolly Chair in Pediatric Nephrology
The Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, PA 19104

Re: Amendment #2 to the Confidentiality Certificate: DK-05-004

Dear Dr. Furth:

This letter amends the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Chronic Kidney Disease in Children Cohort Study (CKiD)."

Specifically, this amendment includes the updated information outlined below.

- The East Coast Clinical Coordinating Center relocated from Johns Hopkins University School of Medicine to the Children's Hospital of Philadelphia (CHOP). Dr. Furth has assumed the position of Division Chief of Pediatric Nephrology at CHOPS.
- Due to many subjects progressing to ESRD it is projected that approximately half of the cohort would still be active by July 2013 and in order to meet the proposed aims of the study it re-opened enrollment for an additional 280 children in early 2011.

The Principal Investigator remains Dr. Susan Furth.

The expiration date of the Certificate has been extended until July 31, 2018.

Please attach this amendment to the original Certificate.

If you determine that the research project will not be completed by the new expiration date, July 31, 2018, it will be necessary to submit a written request for an extension of the Certificate **three months prior to the expiration date**. Any such request must include the justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project. In addition, IRB approval must be maintained throughout the length of the study. Approval must be current and unconditional, or conditioned only upon the issuance of a Certificate of Confidentiality and documented by a letter or form signed by an authorized IRB representative.

Correspondence should be sent to:

Francisco O. Calvo, Ph.D.
Chief, Review Branch
6707 Democracy Boulevard, Room 752
Bethesda, MD 20892-5452
(301) 594-8897

Sincerely,

Gregory G. Germino, MD
Deputy Director, NIDDK