DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institute of Health

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

Month, Date, Year

Dear Dialysis Facility,

As you may know, the United States Renal Data System (USRDS) periodically conducts special studies involving original data collection from patients and/or medical records. The current special study is entitled the Comprehensive Dialysis Study (CDS). The CDS will select a nationally representative cohort of incident hemo- and peritoneal dialysis patients, and collect clinical information above and beyond that available from the Medical Evidence Form and other standard USRDS files. Approximately 3,000 subjects will be contacted for an evaluation of self-reported health status and physical function. Additional studies of self-reported dietary intake and serial laboratory determinations will be conducted on about 900 of the 3,000 subjects. The CDS is a collaborative study designed jointly by the USRDS Coordinating Center and Special Studies Centers in Quality of Life/ Rehabilitation and Nutrition. The co-PIs for the study are Nancy Kutner, PhD, Director, Special Studies Center for Quality of Life/Rehabilitation (Emory) and Glenn M. Chertow, MD, MPH, Director, Special Studies Center for Nutrition (UCSF).

A one stage cluster sampling technique was used to identify facilities for inclusion in the study. Yours was one of the selected facilities. We project that the identified facilities will generate a sufficient number of patients new to dialysis (on maintenance dialysis for at least two months) over a ten month period so that we will achieve a final sample of about 3,000. After informed consent has been obtained from the patient quality of life and physical function questionnaires will be administered at baseline via phone contact. A follow-up survey collecting identical information will be conducted one year after the initial interview. There will be no data abstraction from the medical records.

We have developed our research design after consultation with an ad hoc advisory panel (see attached list of advisory panel members). The major concerns of the panel were burden on facility staff and appropriate IRB oversight. In response to the burden issue NIDDK has allocated additional funding to the study for data collection. Actual data collection will be performed by an experienced research firm, DataBanque, Ltd. We have endeavored to keep the effort from facility staff to a minimum. The IRB clearance issue is discussed below.

Patients will be identified from the CMS REMIS patient tracking system shortly after beginning on dialysis. The USRDS will contact your facility with the names of patients as they are identified. We will supply you with a package of material for each patient, including an informational packet and a patient consent form. A facility staff person will then be asked to present this consent form to the sampled patients with a short description of the project. If the patient has any questions, the consent form will have a toll free

number to call to get additional information. It is important to note that we are not asking the facility staff to consent the patients. The provision of information such as this is allowed by regulations published by the Office of Human Research Protection (OHRP) http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm. (item (B)(3)). A copy of the UCSF IRB clearance for this study is attached.

In approximately one-fifth of the facilities, we plan to collect additional information with respect to nutritional status. Your facility is **not** one of these facilities. If you are interested we can supply you with the additional data collection protocol in those facilities.

We believe that the burden on facility staff will be minimal. The staff in your facility will be asked to give patients a consent form and read a short script describing the study. Because we will be including both hemodialysis and peritoneal dialysis patients we would like the peritoneal patients to be given the information when they come in for routine visits. There may also be an occasional phone call from our survey group if there is a problem with contacting a patient. However, the burden should be minimal.

We plan to begin data collection in September, 2005. We appreciate your support for this study. A vital mission of the USRDS is collection of data from such studies, analysis, and dissemination of the results to improve patient care. The important role that you and your staff play will contribute to the success of the program.

If you have any research based questions, please contact Dr. Paul Eggers (301) 594-8305, Dr. Nancy Kutner (404) 712-5561, or Dr. Glenn Chertow (415) 476-2173.

If you have any specific questions regarding the study process or project procedures, please contact the CDS Coordinating Center Sarah Pederson (612) 337-8969.

Sincerely,

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