UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Comprehensive Dialysis Study - Nutrition

Study Sites: Selected Dialysis Units in the United States

Sponsor: National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
Centers for Medicare & Medicaid Services

Investigators:

Glenn M. Chertow, MD	Kirsten L. Johansen, MD
Donna Brogan, PhD	George A. Kaysen, MD, PhD
Allan J. Collins, MD	Nancy Kutner, PhD
D. Jordi Goldstein-Fuchs, DSc, RD	Patricia Painter, PhD

Glenn M. Chertow, MD and his associates are conducting a study of quality of life, activities, nutrition and your medical care before starting dialysis. You are being asked to participate in this study because you have kidney disease and started dialysis within the last six months.

Approximately 1000 persons with kidney disease will participate in this study. Your participation in this study will last for approximately one year.

A. Procedures

If you agree to participate, the following will occur:

1. You will be contacted by phone by a professional interviewer working with the researchers. You can arrange a convenient time to participate in a phone interview.

2. During the phone interview, the professional interviewer will ask questions about your medical history and about your general health, diet, activities and feelings. This will take around 45-60 minutes. You will be asked to complete a similar set of questions about one year later.

3. An additional 15 mL (approximately 1 tablespoon) of blood will be drawn on the same day as your monthly laboratory tests every three months for one year. No extra needle sticks will be required.

4. The blood specimens and other certain medical information about you may be shared with other scientists not at UCSF. We will not give them your name, address or phone number. We will label the specimen we give them with a code number, not your name. Reports about any research will not be given to you or your doctor. Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for genetic research, we will not put the results in your medical record. The research will not change the care you receive. Your specimen will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value.

5. If you decide later that you do not want your blood sample to be used for future research, you can tell us, and we will destroy any remaining blood sample when it is no longer needed for your care. If you do not want your blood sample or medical information to be used for future research, you can call Dr. Chertow at (415) 476-2173 or pager (415) 443-5369, and we will remove your information from the study.

B. Risks and Discomforts

Confidentiality: Participation in research will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your name will not be used in any published reports about this study.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476-1814.

C. Benefits

You will not receive any direct benefit from participating in this study. However, it is hoped that the information gained from this study will help in the treatment of persons with kidney disease who need dialysis in the future.

D. Alternatives

You may choose not to participate in this study. Refusal to participate will not affect your treatment in any way.

E. Payment

If you complete the phone survey, you will receive a check for $25 in approximately 4 weeks.

F. Questions

This study has been explained to you by Dr. Chertow or the person who signed below and your questions were answered. If you have any additional questions, you can call Dr. Chertow at (415) 476-2173 or pager (415) 443-5369.

G. Consent

You will be given a signed copy of this consent form and a copy of the Experimental Subject's Bill of Rights to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without jeopardy to your medical care.

If you wish to participate, you should sign below.

_____	_____
Date	Subject's Signature
_____	_____
Date	Signature of Person Obtaining or Reviewing Consent

White: Study Copy Yellow: Dialysis Clinic Copy Pink: Patient Copy