9. USRDS Data Flow

9.1 Introduction

The United States Renal Data System (USRDS) is funded by NIDDK to collect information on all patients undergoing dialysis in the U.S. Therefore, the USRDS already obtains personal identification data (e.g., Social Security number) on these patients. The FHN clinical centers will provide the USRDS with FHN patient's SSN and Medicare HIC number so that the patient can be linked by matching on the FHN patient ID and alpha code to the deidentified biospecimens of the patient stored in the NIDDK Repository. In addition the USRDS will provide CMS with a list of patients enrolled in FHN trials so that CMS can reimburse the dialysis providers as appropriate (see Section 2.1) for an extra dialysis treatment.

9.2 Procedures and Confidentiality

How to send data – Personal identification data should be sent via the type of courier service that can be tracked and verified for timely receipt. There is no special courier service that must be used. The USRDS office is equipped with a security key entry and the data will be stored in a locked room with restriction access only to key personnel. All USRDS employees have to sign patient privacy confidentiality agreement forms before being allowed to access patient identifiable data.

Who will be receiving the data at the USRDS? – Mr. Shu-Cheng Chen, 914 South 8th Street, Suite D-206, Minneapolis, Minnesota 55404, U.S.A. Phone: 612-347-6332.

Where will the electronic file be stored and with what security? – The electronic file will be stored on a separate external hard drive on a private network and locked with password protection.

How long will this electronic file be kept? – It will be kept indefinitely to allow patients to contact USRDS to request that their stored Repository samples be withdrawn from use in future studies (see Section 9.3). Note that, USRDS already has the SSN of the patient through its own database.

Will the paper copy be shredded or stored? – The paper received from the FHN clinical centers will be shredded by USRDS once it is entered into the USRDS database. The SSN information can also be destroyed by the clinical center once it is successfully sent to USRDS. Although it is recommended that patient personal information be retained at the clinical center until the end of the FHN trials.

9.3 Withdrawal of Patient Consent for Usage of Repository Specimens

Patients who have consented and provided biospecimens (e.g., serum and plasma) to the NIDDK Repository can withdraw their consent for using their samples in research studies. During the study, the patient should make this request to the clinical center that enrolled them, who will then notify the DCC using the patient's ID and alpha code. The DCC will instruct the Repository to destroy this patient's samples. After the study ends

the patient should send a written request to: Mr. Shu-Cheng Chen, USRDS: 914 South 8th Street, Suite D-206, Minneapolis, Minnesota 55404, U.S.A.
and provide their name and SSN. USRDS will use the matched patient ID and alpha code to notify the Repository to destroy this patient's samples.