Chapter II

Access to the USRDS Data

In response to the new USRDS goal of support for investigator initiated research, new and innovative modes of disseminating data to the research community are being developed by the USRDS Coordinating Center staff. This chapter describes the ways in which the USRDS has provided access to its data in the past and the ways this access is being extended under the current project.

The new dissemination methods include the creation of several types of data files that contain data from the USRDS Annual Data Reports and from USRDS Special Studies. While the overall objective is to make the data widely available to researchers, several important criteria have been considered in the development of these files. These criteria include:

Ease of use. It is important that data disseminated to researchers be easy to use. There should not be a long and steep learning curve associated with learning to work with USRDS data files. Computer compatibility, both in terms of hardware and software, has been a major consideration in the development of USRDS data files for use by outside investigators.

Relevance. Data files need to include data that are in demand by the renal research community. For instance, there has been significant demand for data from the USRDS Special Study of Case Mix Severity and a Standard Analysis File has been developed in order to make these data widely available to the research community.

Cost. Data files created for use by the research community need to be affordable.

Confidentiality. The files must preserve the confidentiality of the patient-specific data in the USRDS database.

How to Get More Information

Table II-1 provides a contact list for the USRDS. Substantive questions not covered by this Annual Data Report should be directed to the Data Request Contact. Questions about the Annual Research Files, Standard Analysis Files, Tailored Data Files or about the database in general should be directed to the Data File Contact person. The Coordinating Center also maintains a mailing list of persons interested in using USRDS data.

List of USRDS Contacts

CONTACT	ADDRESS	PHONE/E-MAIL
Project Officer NIDDK	Lawrence Y.C. Agodoa, M.D. United States Renal Data System NIDDK 5333 Westbard Ave., Room 3A11 Bethesda, Maryland 20892	Phone (301) 594-7553 Fax (301) 594-7501 *larrya@dvsgate.niddk.nih.gov*
USRDS Coordinating Center (CC)	USRDS 315 W. Huron St. Ann Arbor, MI 48103	Phone (313) 998-6611 FAX (313) 998-6620 *usrds@med.umich.edu*
CC Director	Philip J. Held, Ph.D.	(313) 998-6611 *held@med.umich.edu*
CC Deputy Director	Friedrich K. Port, M.D., M.S.	Phone (313) 998-6611 *portb@med.umich.edu*
CC: Data Request Contacts	Lisa Gillikin Sarah Levin David Stannard Marc Turenne	Phone (313) 998-6611 *usrds@med.umich.edu*
CC: Data File Contact	Randall L. Webb	Phone (313) 998-6608 *rlwebb@med.umich.edu*
		e-mail addresses are in italic

Table II-1

Annual Data Reports

The principal vehicle for disseminating information from the USRDS is the Annual Data Report. This USRDS 1994 Annual Data Report is the sixth report produced, and the fifth to be published as an *American Journal of Kidney Diseases* supplement. Annual data reports constitute the most thorough reporting of data and analyses to the renal community on data contributed by the renal community through HCFA and the ESRD Networks.

The USRDS Annual Data Reports contain almost 400 pages of Reference Tables. These tabulations have been used by many investigators as the basis for published research and abstracts. The Reference Tables cover the following topics:

- Incidence and Prevalence of ESRD
- Methods of Treatment
- Mortality and Causes of Death
- Patient Survival
- The Kidney Transplant Process
- Graft Survival
- Hospitalization
- Institutional Providers of ESRD Service
- Census Population Base

These reference tables are available both in paper form and as PC diskette files. The diskette version of the Reference Tables may be replaced for the 1995 ADR with a set of Annual Research Files (ARFs) on diskette. The ARFs will provide summary data at the maximum level of detail consistent with preserving the confidentiality of the underlying patient data. A later section in this chapter discusses the ARFs in more detail.

Paper and microfiche copies of the USRDS Annual Data Reports are

available through the National Technical Information Service (NTIS). Persons interested in these products should contact NTIS, United States Department of Commerce, Springfield, Virginia, 22161, (703) 487-4650. The diskette version of the Reference Tables is available from the USRDS CC (See Data File Contact in Table II-1).

Annual Mortality Rate Methodology

The USRDS has developed a methodology for calculating annual mortality statistics for ESRD patients. Rates of deaths per 1000 patient years at risk are published every year in the Annual Data Report and are grouped according to sex, age, race, primary cause of ESRD, and modality of treatment. Chapter XV of this 1994 ADR provides a detailed description of this methodology.

The availability of published mortality tables allows dialysis and transplant units and ESRD Networks to compare their mortality rates with the national rates published by the USRDS. The USRDS methodology includes computation of Standard Mortality Ratio (SMR), which is a comparative measure of mortality, adjusted for age, sex, race, primary diagnosis and treatment modality. SMRs are used to standardize observed mortality in specific patient subgroups relative to the national death rates.

The USRDS is working toward development of an SMR methodology that adjusts for other meaningful comorbid conditions such as hypertension, a previous history of cardiac disease, peripheral vascular disease, and other conditions.

Data Requests

The USRDS has a primary objective of making data available to the renal community. One of the important means of making data available is through timely response to data requests made by researchers, practitioners and other members of the renal community. From the inception of the USRDS in May 1988 through December, 1993, CC staff have responded to over 500 formal requests for data, plus hundreds more requests for general information on the USRDS and its publications.

In many cases these requests can be answered by providing data published in the Annual Data Report or elsewhere. Requests for data not available in the Annual Data Reports which require two hours or less of computer programmer/analyst time can be completed by the Coordinating Center, almost always within 1-2 days of the request.

Requests that require more than two hours of computer programmer/analyst time will be undertaken only upon written approval by the NIDDK Project Officer

Research needs which cannot be met by the ADR or by 2-hour data requests probably can be met using the Annual Research Files (ARFs), Standard Analysis Files (SAFs), or Tailored Data Files described later in this chapter. In five cases over the past 6 years, the USRDS has, at the request of the Project Officer, created data files for use by other researchers. In the future, most such requests will be met by the SAFs.

The USRDS CC also responds to requests for data from government agencies such as Centers For Disease Control and Prevention as well as from the NIDDK.

Requests that are not within the scope of the USRDS project objectives are referred directly to HCFA.

Annual Research Files

As mentioned earlier, the USRDS Annual Data Reports have included almost 400 pages of statistical Reference Tables aggregated from the USRDS database. The USRDS CC has proposed supplementing or partially replacing the Reference Tables with a set of public use Annual Research Files (ARFs). These files would be publicly available at low cost and would be on PC diskettes in a format which readily can be used by a wide variety of PC software.

The ARFs would support most of the analytical methodologies used in the ADR and would be designed to provide the maximum level of detail which is consistent with protecting the confidentiality of the underlying patient data.

These confidentiality requirements would be met by providing only aggregated data in the ARFs and by aggregating so that no cell represents fewer than 10 patients. In many cases multiple files would be provided, each of which would provides a different mix of detail. For instance one file of mortality rates might provide five-year age groups by sex by two race groups by four primary disease groups by year. Another might group three years in order to provide additional detail by race. Another might use only four age groups, two race groups, and two primary disease groups in order to provide rates by ESRD Network.

Before undertaking the substantial development effort involved in the ARFs, the USRDS CC needs to determine whether there is adequate demand for such files. The ARFs represent an intermediate step between the current Reference Tables and the underlying patient specific data provided by the Standard Analysis Files (see next section). The ARFs provide less detail than the SAFs but have the advantages of public access, no application and approval process, and very low cost.

Is there a need for such files, or would most investigators prefer to go the extra step and use the SAFs? If your answer is yes, contact the Data File Contact person (see Table II-1) by phone, FAX, mail, or e-mail. Please be sure to include your address, phone, and e-mail address. The decision to proceed with development of the ARFs may depend largely on the responses received by the CC.

Standard Analysis Files

While the ARFs would meet some research needs, other research requires access to the underlying patient-specific data. The USRDS Standard Analysis Files (SAFs) are designed to meet the needs of most such research at minimal cost to the researcher. As of June, 1994, four requests for SAFs have been filled.

The SAFs are governed by the USRDS Policy on Data Release for Investigator Initiated Research and the USRDS Agreement for Release of Data, which appear at the end of this chapter. While the ARFs are publicly available, use of the SAFs requires that the

research investigator's proposal be approved and that the researcher agree in writing to observe the prescribed restrictions.

Most SAFs provide patient-specific data. All patient identifiers (Name, address, SSN, Medicare beneficiary ID, etc.) are removed from the files or are encrypted, but the confidentiality of the data is still a serious concern. The Agreement for Release of Data therefore includes restrictions on the use and disposition of the SAFs. The SAFs do include an encrypted ID number to allow multiple SAFs to be merged when needed.

Content of Standard Analysis Files

Table II-2 lists the currently available and planned SAFs. The two central files are the Patient file and the Treatment History file. The contents of both files are discussed in greater detail in Chapter XIV, "Guide to the USRDS Database."

Patients

The Patients file has one record per patient in the USRDS database and gives the basic demographic and ESRD-related data about the patient. Data from the Patients file are included in the Transplant and Special Study SAFs to reduce the need for the user to merge files. The Patients SAF also includes a Residence file which provides a longitudinal record of place of residence for each patient.

Treatment History

The Treatment History file is also referred to as the Modality Sequence file. For each patient, this file has one record per spell on a single modality from a single provider. The Transplant SAF and each of the Special Study SAFs include a file with the Treatment History records for the patients in that SAF.

Transplant

The Transplant SAF contains one record for each transplant in the USRDS database. For patients with more than one transplant, there will be one record for each transplant for that patient. These transplants will appear together in the file and can be linked based on the encrypted patient ID number. The order of the transplants is indicated by the transplant dates.

Hospital

The Hospital SAF contains one record for each hospitalization for each patient. Chapter XIV, "Guide to the USRDS Database", discusses some of the limitations of the hospitalization data. The Hospitalization SAF can be linked to the Patient and Treatment History SAFs based on the encrypted patient ID number.

USRDS Special Studies

SAFs have been created for three of the USRDS Special Studies: CAPD Peritonitis, Pediatric Growth and Development, and Case Mix Severity. The SAF from the Case Mix Adequacy Special Study will be available in two stages: 4000 cases by August, 1994, and the full 6000 by June, 1995. See also Chapter XIII, "USRDS Research Studies."

USRDS Standard Analysis Files

File Name	SAS File Names	Unit of Observation	Uses
Patient	PATIENTS	Patient	Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted ID.
Residence	RESIDENC	For each patient, one record for each period in a different residence.	Regional analyses
Treatment History (Modality Sequence)	MODSEQ	Patient. One record for each spell a patient spends on one modality	Modality distribution and treatment patterns. Permits an easy determination of treatment modality at a point in time and changes in modality over time.
Hospital	HOSP	Patient hospital stay	Hospitalization analyses
Transplant	TX	Transplant. Can have multiple transplants for one patient.	Transplant and transplant outcome analyses. Includes file of denominators for rates of transplantation per patient year on dialysis.
Transplant Follow-up	TXFU	For each patient, one record for each follow-up form filed. Should be filed at discharge, 6 months, 12 months, then annually.	Immunosuppressive therapy, rehabilitation, rejection episodes.
Case Mix Severity (USRDS Special Study)	CASEMIXS	Patient. One record for each patient in the study.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values.
Pediatric Growth and Development (USRDS Special Study)	PEDGROW	One record for each patient in the study.	Growth, development, and other issues relating to pediatric ESRD Patients
CAPD Peritonitis (USRDS Special Study)	CAPD	One record for each patient in the study.	CAPD and peritonitis.
Case Mix Adequacy (USRDS Special Study)	ADEQUACY	One record for each patient in the study	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values. Initial file of 4000 cases available 8/94. Full 6000 cases available 6/95.
Facility	FACILITY	One record for each year during which each facility was in operation	Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics.
Annual Summary	PATSUM	One record for each year during which a patient was alive at some time.	End of year point prevalence, modality distribution, denominators for rates of transplantation per patient year on dialysis.

Table II-2

File Media and Formats

The SAFs are provided as SAS (Statistical Analysis System) transport data files on 9-track 6250 BPI magnetic tape. They may also be provided as SAS system data sets on 3.5 inch high density PC diskettes for those files which are small enough to make this format practical. Each SAF may actually include multiple SAS data sets, and all include the SAS formats used by these files.

In order to keep the SAFs affordable, the files are provided only in SAS format. Researchers who require a different format are responsible for arranging for the conversion themselves and should have little difficulty obtaining help in doing so from any university computer center.

SAS format was chosen for the USRDS SAFs because it is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system which runs on most types of computers from mainframes to PCs. It is almost universally available on university computer systems. SAS transport data files produced on the USRDS VAX computer can be used by SAS on any other computer which runs SAS. They can also be read by the Statistical Package for the Social Sciences (SPSS), another leading data management and statistical analysis system. The USRDS SAFs take full advantage of the ability of SAS data sets to incorporate a large amount of documentation into the file.

What You Need in Order to Use the SAFs.

Computer: Any computer on which SAS runs.

Disk Storage: Between 10 megabytes and 400 megabytes depending on the files being used. You could also store the SAS files on tape. The R*esearcher's Guide to the USRDS Database* provides more detailed specifications of file size.

Software: SAS

Tape Drive: a 9-track 6250 bpi tape drive. Smaller SAFs may be supplied on high density 3.5 inch PC diskettes.

People with SAS experience: The SAF documentation provides some of the basics of loading the files into SAS and using them, but you will need people with SAS experience. The USRDS CC cannot provide technical assistance with running SAS.

Price

The price of the files is intended to cover the incremental cost of reproducing and shipping the file and documentation, the administrative cost of handling the sales of the files, and the cost of technical support to researchers in selecting the correct files and in using the files.

The SAFs are provided in "packages" as shown in Table II-3. Each package includes a main SAF and, in most cases, one or more additional files. In some cases, the additional file is a complete SAF, but other files may be subsets of the records in another SAF for the patients in the main SAF. Thus, each of the USRDS Special Study SAFs also contains subsets of the Residence, Hospital, and Treatment History SAFs

Individual SAFs Included in the SAF Packages

	Subsets of Other SAFs for Patients in Main File			Supplementary SAFs		
Main SAF (Package Name)	Residence	Hospital	Treatment History	Transplant Follow-up	Facility	SAS Formats
Patient	✓					✓
Treatment History					✓	✓
Transplant	✓	✓	✓	✓	✓	✓
Hospital						
Annual Summary						✓
CAPD Peritonitis	✓	✓	✓			✓
Case Mix Severity	✓	✓	✓			✓
Pediatric Growth	✓	✓	✓			✓
Case Mix Adequacy	✓	✓	✓			✓

Table II-3

that include only the records for the patients in that Special Study. Each package fits on one magnetic tape except for the Hospital SAF (3 tapes) and the Transplant SAF (2 tapes).

The prices have been set at $536 for the first package and $119 for each additional package in one request.

Documentation

The *Researcher's Guide to the USRDS Database* is included with the documentation of each SAF. If multiple SAFs are ordered, then a technical memo about linking the SAF files is included. The remaining documentation generally includes the following elements:

- SAS PROC CONTENTS listing variables on the file, number of observations, etc.
- USRDS Data Dictionary listing of variables on the file giving more information about each variable, including crossreference with the data collection forms.
- Sample SAS code for loading the data from the transport file.
- Data collection forms used by the study
- Tabulation of the distribution of values for categorical variables and univariate statistics for continuous variables.
- Discussions of the following issues: the study objectives, sampling methodology, editing performed on the raw data, and derived analytical variables which may be included in the file.
- Copies of publications which have already resulted from this study.

Tailored Data Files

If the Standard Analysis Files do not meet the investigator's needs, the USRDS can also respond to approved investigator-initiated data requests by providing a data file created to the

investigator's specifications. The investigator will pay for the cost of computer, programmer and researcher time to generate the requested data file. Costs will vary depending on the size and complexity of the data requested and will be substantially higher than the cost of the Standard Analysis Files. The Data File Contact person listed at the beginning of this chapter can help you determine whether your research needs can be met by an existing SAF or whether a tailored file is needed.

Papers, Abstracts, and Publications

As the USRDS has matured, presentations and publications have become an important additional vehicle for communicating biomedical findings to the scientific community. Formal dissemination of this type reaches the largest possible audience by becoming part of the literature. Findings are then available to interested parties through many bibliographic sources. Moreover, the process of peer review preceding acceptance adds another measure of quality control to the careful internal review that is given to all USRDS products. Appendix A lists USRDS presentations and publications through March, 1994.

Proposing Studies to be Carried Out by the USRDS CC

A portion of USRDS resources is used to carry out a number of existing data studies each year. Anyone may propose an existing data study, to be conducted by USRDS CC staff, often in collaboration with outside researchers. Proposals should be directed to the NIDDK Project Officer. A suggested form appears at the end of this chapter.

Study proposal submissions must summarize the goals of the research, study design, approximate sample size needed, data to be included, anticipated schedule for completion, and investigators. Depending on the nature of the research proposed, one or more of the USRDS advisory committees may review the research proposal and make written recommendations to NIDDK for prioritization and approval.

Acknowledgment for Use of USRDS Data

All users of USRDS data should acknowledge that use. Publications that use USRDS data should include such acknowledgment and the following notice:

The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. Government.

Policy on Data Release for Investigator Initiated Research

Since the Standard Analysis Files and tailored data files contain confidential, patient specific data, release of these files requires the approval process described in this section. The investigator may contact the USRDS Project Officer (PO) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to discuss his/her data request before preparing a written proposal. (See Table II-1 for

USRDS contact list). To request research data files for analysis from the USRDS:

1. The investigator will provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation. This may be the project description from an application for a grant or for other sources of other funding. The project summary must include goals, background data, an in-depth description of the study design and analytic methodology, and resources available for completing the project. It is necessary for the proposed project to comply with the Privacy Act of 1974, and the project summary should provide enough information to enable assessment of compliance. The guidelines for adherence to the Privacy Act are contained in Section F of the USRDS Agreement for Release of Data which is provided at the end of this chapter. Also located at the end of this chapter is the suggested format of the project summary.

2. The proposal must indicate which USRDS Standard Analysis Files will be needed, and must provide for sufficient funding to cover the cost of the data files, as determined from the SAF price list. If the USRDS Standard Analysis Files cannot meet the requirements of the proposed research, the proposal must specify precisely which data elements are needed, and must budget for a substantially higher cost for obtaining the files. The investigator may contact the USRDS CC with questions about the files. (See Data File Contact in Table II-1)

3. The project will be reviewed by NIH for technical merit and for conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the approval or disapproval, discussing the reason for the disapproval. The PO will send a copy of approval letters to the USRDS CC. The process of reviewing the written data request, generating the data file, and releasing the data will take approximately three months.

4. After approval, the investigator will return a signed copy of the USRDS Agreement for Release of Data to the PO. The investigator and the USRDS CC will resolve any technical questions. The investigator will arrange payment with the USRDS CC, and payment must be received before the files will be released.

5. When both a copy of the fully executed Agreement for Release of Data, and payment for the files, have been received by the USRDS CC, the CC will prepare the files and documentation and will send the files and documentation to the PO, who will release the materials to the investigator.

6. Any reports or articles resulting from use of the USRDS data must be submitted to the PO, prior to submission for publication, for review to assure adherence to the Privacy Act. The PO must respond within 30 days. If the report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance with the Act is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators. On the other hand, approval does not indicate endorsement of the opinions and conclusions of the investigators by the government.

7. All publications using the released data must contain the standard disclaimer, "The data reported here have been supplied by The United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the United States Government." The investigator is requested to send copies of all final publications resulting from this research to both the PO and the USRDS CC.

Caveats

1. This policy establishes conditions and procedures for the release of data from the USRDS and is intended to ensure that data are made available to investigator(s) in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research. The USRDS data are intended to supplement (and not replace) public use files produced by the Health Care Financing Administration (HCFA). Data file requests that may be satisfied by any of the HCFA public use files will be referred to that agency.

2. The USRDS will not release data which identify individual patients, providers, or facilities. If individually identifiable data are needed, the request should be submitted directly to the Health Care Financing Administration for processing. However, since it might be possible to infer the identity of individual patients, providers, or facilities from the data in the Standard Analysis Files, the data in these files are considered confidential. The USRDS Agreement for Release of Data contains a number of both general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions.

3. Use of these data to identify and/or contact patients, facilities, or providers on the files is prohibited by USRDS Policy. Identifying or contacting patients is also prohibited by the Privacy Act of 1974.

4. The USRDS CC will provide data in any of the usual forms, such as on tape, disk, and/or hard copy. Analysis services by the USRDS CC (other than to review the proposal and to prepare the data file if approved by the PO) will not be provided for these data requests under the USRDS contract. However, USRDS CC personnel may participate in analyses funded by other sources.

5. Standard Analysis Files or other data files from USRDS Special Studies will become available one year after the data have been collected, edited, and entered into the database.

UNITED STATES RENAL DATA SYSTEM (USRDS)

AGREEMENT FOR RELEASE OF DATA

In this agreement, "Recipient" means _____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copy containing data extracted from the USRDS research database.

B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.

C. The Recipient shall not use the data to identify individuals on the file.

D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.

E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. The purposes for which the data may not be used include, but are not limited to:

- identification and targeting of under- or over-served health service markets primarily for commercial benefits;
- obtaining information about providers or facilities for commercial benefit;
- insurance purposes such as redlining areas deemed to offer bad health insurance risks; and
- adverse selection (e.g., identifying patients with high risk diagnoses).

Any use of the data for research not in the original proposal must be approved by the PO.

F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping) and no cells (aggregates of data) contain information on fewer than 10 individuals or fewer than 5 providers or facilities. The Recipient shall not publish or otherwise disclose data which identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Office (PO) that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor and (2) the contractor has signed a data release agreement with the PO

G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement

prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.

H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written accounting of all such copies and derivative files made, which it will furnish upon request to the PO. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient's expense, and any derivative files and any copies shall be destroyed.

J. Authorized representatives of the PO and/or of HCFA will, upon request, be granted access to premises where data in this file are kept for the purpose of inspecting security procedures and arrangements.

Revised June 1994

Signatures:

_____

(Recipient typed name, title, and organization)

_____

(Recipient telephone number)

_____

(Recipient signature) (Date)

_____

(Contractor typed name, title, and organization)

(As appropriate)

_____

(Contractor telephone number)

_____

(Contractor signature) (Date)

Lawrence Agodoa, M.D., NIDDK, NIH or

Camille A. Jones, M.D., NIDDK, NIH

(USRDS Project Officer typed name and organization)

_____

(USRDS Project Officer Signature)(Date)

RESEARCH PROPOSAL TO THE U.S. RENAL DATA SYSTEM

Suggested Outline

I. RESEARCH TOPIC TITLE:

II. BACKGROUND:
- A. Hypotheses
- B. Objectives

III. STUDY DESIGN:

IV. CLASSIFICATION: (Please cite all that apply.)
- A. Existing data study/special data study (requires new collection)/unsure
- B. Retrospective/Historical prospective
- C. Cross sectional/Longitudinal
- D. Incidence/Prevalence cases
- E. Mortality data/Morbidity data
- F. Other (specify):

V. DESCRIPTION:

VI. DATA:
- A. Study variables needed
- B. Source(s)

VII. PROPOSED BY:
- A. Name
- B. Affiliation
- C. Phone and fax

VIII. PROPOSED CO-AUTHORS:
- A. Name
- B. Affiliation
- C. Phone and fax

IX. DATE SUBMITTED:

Please send to:
Lawrence Y.C. Agodoa, M.D.
USRDS Project Officer
NIH/NIDDK/DKUHD
5333 Westbard Avenue, Room 621
Bethesda, MD 20892