

Chapter I

The USRDS and Its Products

This is the seventh *Annual Data Report* of the United States Renal Data System (USRDS), which began operations in 1988. The USRDS is operated by the National Institute of Diabetes and Digestive and Kidney Diseases in conjunction with the Health Care Financing Administration. This national data system collects, analyzes, and distributes information about end-stage renal disease (ESRD) in the United States. It includes comprehensive data needed to describe the incidence and prevalence of treated ESRD, modality of treatment (including both dialysis and kidney transplantation), causes of death, patient survival, hospitalization and institutional providers of ESRD treatment.

Project Goals

Since its inception in 1988, the USRDS has had four primary objectives:

- Design and implement a consolidated renal disease data system that will provide the biostatistical, data management and analytical expertise necessary to characterize the total renal patient population, and to describe the distribution of patients by sociodemographic variables across treatment modalities.
- Report on the incidence, prevalence, mortality rates and trends over time of renal disease by primary diagnosis, treatment modality and other sociodemographic variables.
- Develop and analyze aggregate data on the effect of various modalities of treatment by disease and patient group categories. These data will be used to analyze the prevention and progression of renal disease with special emphasis on morbidity and mortality.
- Identify problems and opportunities for more focused special studies of renal research issues

currently not addressed by the consolidated data system.

With the start of the second five year contract in July 1994, the USRDS added two additional primary objectives:

- Conduct cost effectiveness and other economic studies pertaining to biomedical and epidemiological aspects of ESRD.
- Support investigator-initiated research by making data from the database widely available in convenient formats to the biomedical and economic research community.

Organizational Structure

The USRDS is funded and directed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services is a major contributor to the project, providing expertise and most of the primary data in the system. The Health Care Financing Administration also funds the cost-effectiveness and economic studies performed by the USRDS.

The USRDS is operated by a Coordinating Center (CC) at the University of Michigan in Ann Arbor. Figure I-1 shows the organization of the USRDS. The USRDS is managed and operated through the collaborative efforts of all of the organizations and committees listed on pages v-ix of this report.

NIDDK's Division of Kidney, Urologic and Hematologic Diseases (DKUHD) oversees the USRDS, ensuring that the scientific and technical goals of the USRDS are consistent with the mission and responsibilities of NIDDK and NIH. The NIDDK Project Officer has responsibility for

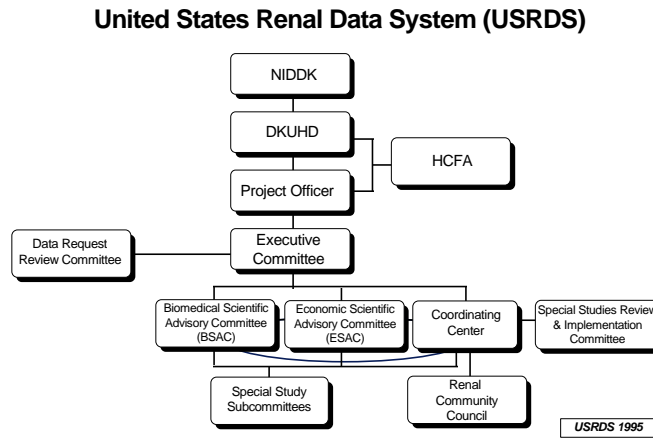


Figure I-1

USRDS organization chart.

monitoring the Coordinating Center's technical progress in meeting the six primary objectives.

A HCFA Project Coordinator directs cost-effectiveness and economic studies performed by the Coordinating Center, and assists with other issues related to the USRDS project. While the NIDDK must approve all cost-effectiveness and economic topics, the HCFA Project Officer directly supervises all such projects.

USRDS Committees

NIDDK makes all final decisions regarding the studies pursued by the USRDS as implemented by the CC. Seven major committees have assisted in this process by providing advisory input to NIDDK and the CC:

The **Scientific Advisory Committees (SACs)** draw on the expertise of researchers and practitioners in the fields of ESRD research, pediatric nephrology, quality of life, transplantation, hemodialysis, peritoneal dialysis, biostatistics, epidemiology and health economics. The Biomedical SAC (B-SAC) has the role of providing epidemiological, clinical and biostatistical advisory input to the NIDDK and the CC, while the Economic SAC (E-SAC) has the role of providing economic advice to the NIDDK, HCFA, and the CC. Both of the Scientific Advisory Committees recommend priorities for research by the USRDS. In doing so, they review and make recommendations to NIDDK (for biomedical issues) and HCFA (for economic issues) on proposed special studies and on findings of studies conducted by the USRDS. Fulfilling these responsibilities

requires individuals who have a broad understanding of the issues surrounding renal research.

The USRDS **Executive Committee (EC)** is comprised of the NIDDK Project Officer, the HCFA Project Officer, a staff member from HCFA, the Chairperson of the Biomedical Scientific Advisory Committee, and the Director and Co-Director of the Coordinating Center. Its role is to advise the NIDDK Project Officers on the overall data management and research plan, to ensure cooperative participation among all components of the project, and to identify and address any other major issues related to the project.

The **Renal Community Council (RCC)** is comprised of more than 30 professional/scientific/advocacy groups with an interest in ESRD and the USRDS. The USRDS makes a presentation to the RCC at the annual meeting of the American Society of Nephrology. The RCC also provides feedback and advice to the CC, which transmits this information to the NIDDK Project Officer.

The **Data Request Review Committee (DRRC)** serves in an advisory capacity to the Project Officer. It was established in mid-1991 and includes representatives from NIDDK, HCFA, and the CC. (When they are needed, two additional reviewers are selected from the SAC.). Since making data available to investigators in the community will be a major focus of the USRDS during years six through ten, the DRRC will play an important role in the review of data requests and will make recommendations to the

List of USRDS Contacts

CONTACT	ADDRESS	PHONE / e-mail
NIDDK Project Officer	Lawrence Y.C. Agodoa, M.D. United States Renal Data System NIDDK Natcher Building - 6AS-13B 45 Center Drive - MSC 6600 Bethesda, Maryland 20892-6600	Phone (301) 594-7717 Fax (301) 480-3510 agodoal@ep.niddk.nih.gov
NIDDK Deputy Project Officer	Camille Jones, M.D., MPH United States Renal Data System NIDDK Natcher Building - 6AS-13B 45 Center Drive - MSC 6600 Bethesda, Maryland 20892-6600	Phone (301) 594-7717 Fax (301) 480-3510 jonesc@ep.niddk.nih.gov
USRDS Coordinating Center (CC)	USRDS 315 W. Huron St., Suite 240 Ann Arbor, MI 48103	Phone (313) 998-6610 FAX (313) 998-6620
CC Director	Philip J. Held, Ph.D.	(313) 998-6611 held@umich.edu
CC Deputy Director	Friedrich K. Port, M.D., M.S.	Phone (313) 998-6611 portb@umich.edu
CC: Data File Contact	Randall L. Webb	Phone (313) 998-6608 rlwebb@umich.edu
Standardized Mortality / Hospitalization Rate Methodology	Robert Wolfe, Ph.D	Phone: (313) 998-6124 bobwolfe@umich.edu
CC: Data Request Contact Publication orders	Dora Smith	Phone (313) 998-6611 adorable@umich.edu
Internet World Wide Web		http://www.med.umich.edu/usrds/

Table I-1

Project Officer concerning the appropriateness of the data requests.

The DRRC reviews requests to the USRDS for release of data files to supplement any research files produced by HCFA or the Coordinating Center for use by the research community. This helps to ensure that USRDS data are made available to investigators in the pursuit of legitimate biomedical and economic research.

The **Special Studies Review and Implementation Committee (SSRIC)** is chaired by HCFA and is comprised of staff from the NIH, HCFA

and the CC, as well as one representative of the ESRD Networks. The SSRIC's focus is on the design, implementation and progress of USRDS Special Studies.

The USRDS Database

The Health Care Financing Administration (HCFA) provides most of the existing data in the USRDS database. In addition to all of the data from its ESRD Program Management and Medical Information System (PMMIS) and the Annual Facility Survey, HCFA shares data on transplant follow-up and Medicare Parts A and B services

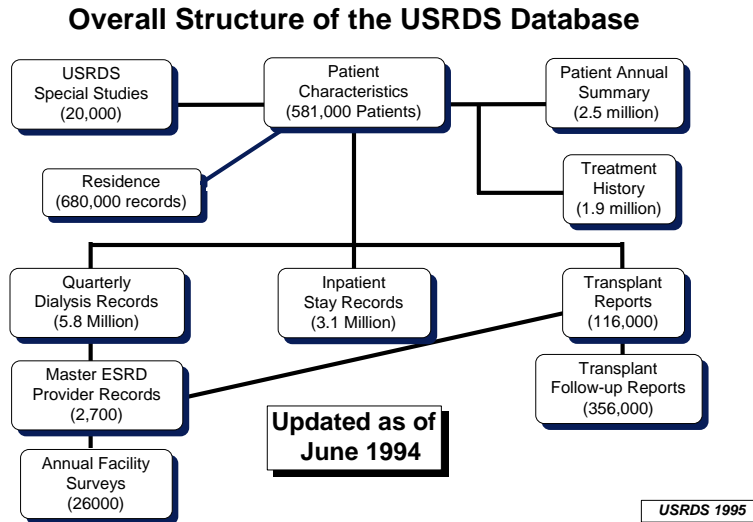


Figure I-2

Overall structure of the USRDS research database with counts of patient and facility records as of May, 1993.

derived from Medicare claims. These HCFA supplied data are used to form the core of the USRDS database, which is summarized in Figure I-2. In fulfilling the objective of performing cost-effectiveness and other economic studies, the USRDS is now incorporating HCFA reimbursement data contained in the National Claims History Files.

In addition, HCFA helps the USRDS with Special Studies. Most of the new, primary data for Special Studies are collected through the 18 ESRD Networks, which are funded by HCFA under separate contracts. Chapter XIII describes these studies in some detail. Data from the Special Studies are fully integrated into the USRDS database. Data collection began in March 1995, for an important new USRDS Special Study, the Dialysis Morbidity and Mortality Study. Data not otherwise contained in the USRDS database will be collected from a national sample of 24,000 patients drawn from all dialysis units. These data will support research initiatives important to the prevention and treatment of ESRD.

Since July 1990, selected data on non-Medicare patients treated by United States Department of Veterans Affairs (DVA) facilities have also been incorporated into the USRDS database. Starting in July 1994, HCFA and the Health Resources and Services Administration (HRSA) have consolidated the collection of transplant data collections by HCFA and by the United Network for Organ Sharing (UNOS) into a single expanded data collection by

UNOS under its contract with HRSA. The expanded transplant data will be shared among HRSA, HCFA and NIH, and will thus become available to the USRDS. The HRSA-collected transplant data includes information for non-Medicare as well as Medicare patients.

Data in the USRDS database collected by HCFA's ESRD Networks, federal insurance carriers and fiscal intermediaries are supplemented by data from the Social Security System, the United States Bureau of the Census, local and national ESRD provider databases and from international ESRD registries. In the long term, there are plans to explore the feasibility of including or linking data from other existing provider databases.

The USRDS database is updated every year, with the last update taking place in the Fall of 1994, using data collected through June of 1994. Because of delays in processing of data through the Medicare system, the USRDS generally has waited 15 months before reporting patient specific data for a given time period. This explains why most of the Reference Tables in this 1995 ADR generally report data through December, 1992. Tables in which this "15 month rule" is relaxed are clearly noted and are generally labeled preliminary. Data from the HCFA Annual Facility Surveys are current through 1993. In addition, this ADR includes projections of incidence and prevalence through the current year.

The discussion below of the USRDS Standard Analysis files provides a good overview of the USRDS database. The *Researcher's Guide to the USRDS Database* provides more detailed documentation of the database (see Table I-2).

USRDS Products

Table I-2 shows the various "products" of the USRDS through which the USRDS disseminates the results of ESRD research to the renal community and to the general public and provides data to support ESRD research. Except where a cost is mentioned in Table I-2, these products are provided on request without charge. Table I-1 provides a list of specific contacts for further information about various aspects of the USRDS.

USRDS on the Internet World Wide Web

Since October, 1994, the Reference Tables from the 1994 ADR have been available on the Internet via a Gopher server. The USRDS now has a World Wide Web home page at <http://www.med.umich.edu/usrds/> which provides a variety of information in addition to the Reference Tables from this 1995 ADR. In fact, the Reference Tables are available electronically before they are distributed on paper!

SMR/SHR 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 XIV provides a 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 February, 1995, 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, usually within 1 week of the request depending on work load.

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 Standard Analysis Files (SAFs), or Custom Data Files described later in this chapter. Requests for Medicare ESRD program data that are not within the scope of the USRDS project objectives are referred directly to HCFA.

USRDS Products

For ESRD Researchers and for the General Renal Community

Annual Data Reports	The principal vehicle for dissemination of USRDS data. Available in print and microfich from the National Technical Information Service (NTIS), United States Department of Commerce, Springfield, Virginia, 22161, (703) 487-4650.. Text portion of the report will be published in the <i>American Journal of Kidney Disease</i> .
<i>USRDS GoldNotes</i>	An occasional newsletter describing USRDS activities and summarizing results of USRDS research
Internet World Wide Web	The Reference Tables of this ADR, the <i>USRDS GoldNotes</i> , and other USRDS publications are available electronically on the Internet using World Wide Web at http://www.med.umich.edu/usrds/
Diskettes of ADR Tables	These diskettes are provided for those who cannot easily download the tables from the Internet.
Data Requests	The USRDS CC staff respond to more than 100 requests for data and for general information about the USRDS each year. Limited resources are available for simple computer tabulations.
<i>Guide to the USRDS SMR/SHR Methodology</i>	Chapters V, IX and XIV describe the USRDS Standardized Mortality Rate (SMR) and Standardized Hospitalization Rate (SHR) methodologies. The <i>SMR/SHR Guide</i> will be a collection of articles about these methodologies and how they can be used to compare local outcomes with national norms for quality improvement purposes.
<i>Researcher's Guide to the USRDS Database</i>	This <i>Guide</i> is the basic reference for researchers who use USRDS data files. It provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files.
Standard Analysis Files	These data files provide patient-specific data from the USRDS database to support ESRD research, at an affordable price. User must sign a data release agreement with NIH. More information is provided in this chapter and in the <i>Researcher's Guide</i> .
Custom Data Files	For research needs not met by the Standard Analysis Files. Researcher pays costs of production and must sign a data release agreement.
Papers, abstracts, and publications	Most USRDS research studies result in published papers or presentations at professional meetings. A list of publications and presentations is in Appendix A.

To request any of these products, contact the USRDS Coordinating Center at (313) 998-6611 or by e-mail at usrds@umich.edu, or see the Contact List in Table I-1. Products are provided without charge except as mentioned in the descriptions above.

Table I-2

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.

Standard Analysis Files

The USRDS Standard Analysis Files (SAFs) are designed to meet the needs of most such research at minimal cost to the researcher. As of February, 1995, thirteen requests for SAFs have been filled.

The SAFs are governed by the USRDS Policy on Data Release for Investigator Initiated Research, which appears at the end of this chapter. Use of the SAFs requires that the research investigator's proposal be approved and that the researcher sign the USRDS Agreement for Release of Data (See the *Researcher's Guide*), agreeing 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 I-3 lists the currently available 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 the *Researcher's Guide*.

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.

The USRDS CC is currently in the process of adding summary cost variables to this file.

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. 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 are currently available, and the full 7000 will be available by June, 1995. See also Chapter XIII, "USRDS Research Studies."

Reimbursement Data

The USRDS CC is currently in the process of adding Medicare reimbursement data to the USRDS database and determining how best to incorporate these data into the SAFs. At a minimum, summary cost variables will be added to the Treatment History and Patient Annual Summary files. Please contact the USRDS CC (see Table I-1) if you have suggestions about how these data should be handled.

USRDS Standard Analysis Files

File Name	Unit of Observation	Uses
Patient	Patient	Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted ID.
Residence	For each patient, one record for each period in a different residence.	Regional analyses
Treatment History	Patient. One record for each spell a patient spends on one modality	Modality distribution and treatment patterns. Treatment modality at a point in time and changes in modality over time.
Hospital	Patient hospital stay	Hospitalization analyses
Transplant	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	For each patient, one record for each follow-up (discharge, 6 months, annually)	Immunosuppressive therapy, rehabilitation, rejection episodes.
Case Mix Severity (USRDS Special Study)	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)	One record for each patient in the study.	Growth, development, and other issues relating to pediatric ESRD Patients
CAPD Peritonitis (USRDS Special Study)	One record for each patient in the study.	CAPD and peritonitis.
Case Mix Adequacy (USRDS Special Study)	One record for each patient in the study	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values. Full 7000 cases available 6/95.
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	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 I-3

Individual SAFs Included in the SAF Packages

Main SAF (Package Name)	Subsets of Other SAFs for Patients in Main File			Supplementary SAFs		
	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 I-4

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 *Researcher's Guide to the USRDS Database* provides more detailed specifications of file size.

Software: SAS, SPSS, or other software which can read a SAS transport data file.

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.

Cost

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 as "packages" of related files, as described in Table I-4. 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 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 current prices are \$536 for the first package and \$119 for each additional package in one request. These prices are subject to change. Checks should be payable to The University of Michigan.

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:

- Codebook of variables on the files.
- Data collection forms used by the study
- Sample SAS code for loading the data from the transport file.
- Tabulation of the distribution of values for categorical variables and univariate statistics for continuous variables.
- Discussions of issues of study objectives, sampling methodology, editing performed on the raw data, and derived analytical variables which may be included in the file.

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 I-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 in the Researcher's Guide to the USRDS Database.

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 I-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 a 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. A copy of the Agreement is contained in the *Researcher's Guide*. 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 sources other than the USRDS contract.

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.

