



USRDS

United States Renal Data System

USRDS DUA Form Instructions

- On the first page of the data use agreement, please fill in your project name. The name should match the project title in your IRB approval letter.
- No changes to the language in items A-J can be made. Requesting these changes will require review by NIH and CMS and will cause significant delays in the approval process
- Requestor organization is the hospital, university or company at which you work and will be housing the datasets

United States Renal Data System (USRDS) Agreement for Release of Data

Project Title

In this agreement, "Requester Organization" means

- All projects will require the Core SAF for ESRD analyses or the CKD 5% Core for CKD analyses.
- The files listed here are all cumulative files; no need to list dates in your proposal for these files
- The items on the right side are all special studies; the years of data collection are noted next to each study

K. The following USRDS Data file(s) is/are covered under this Agreement.

Standard Analysis Files (SAFs) requested:

- | | |
|---|---|
| <input type="checkbox"/> Core | <input type="checkbox"/> Dialysis Morbidity and Mortality Study (DMMS, 1993-1997) |
| <input type="checkbox"/> Transplant | <input type="checkbox"/> Comprehensive Dialysis Study (CDS, 2006) |
| <input type="checkbox"/> Hospital | <input type="checkbox"/> Clinical Performance Measures (CPM, 2000-2008) |
| <input type="checkbox"/> CKD 5% Cohort Core | <input type="checkbox"/> Case Mix Adequacy (CMA, 1990) |
| <input type="checkbox"/> CKD 5% Cohort Hospital | <input type="checkbox"/> Active-Adipose Study (AAS, 2009-2013) |
| <input type="checkbox"/> CROWNWeb Clinical Data | <input type="checkbox"/> Transition of Care in CKD (TCCKD) |

- Please write in the years of claims datasets included in your research proposal if needed for the project. Only the years available next to each claims dataset can be included on the form. The USRDS does not approve DUAs with years of data listed beyond those currently available.

For the following SAFs, indicate the claim year(s) requested as well:

- Institutional Claims (pre-1989 through 2018 available) _____
- Medicare Claims Clinical data (2011-2018) _____
- Physician/Supplier Claims (1991–2018 available) _____
- Part D (2006–2018 available) _____
- Pre-ESRD Institutional Claims (incident years 1995-2018) _____
- Pre-ESRD Physician/Supplier Claims (incident years 1995-2018) _____
- Pre-ESRD Part D (incident years 2008-2018) _____
- CKD 5% Institutional Claims (1992–2018 available) _____
- CKD 5% Physician/Supplier Claims (1992–2018 available) _____
- CKD 5% Part D (2006–2018 available) _____

- The authorized signatory is a person from your legal/contracts department or the head of your specific department who has authority to sign DUAs/contract

Requester Signature (for the Institutional Official for Data Assurance)

Authorized Signatory (Printed name, title & date)

Requester Address

Requester Telephone Number

- At a minimum, the PI of the project and any statisticians should sign the DUA. Any individual that will be working directly on the USRDS SAFs should sign; if personnel change, please **submit additional signature pages** to amend your approved project.

Read and Acknowledged (for Primary Investigator and all co-investigators who will analyze data directly)

Investigator / Analyst signature	Name	Date
Investigator / Analyst signature	Name	Date
Investigator / Analyst signature	Name	Date
Investigator / Analyst signature	Name	Date

(Attach additional signature pages as necessary)

Checklist:

DID YOU REMEMBER TO:

- Signed copy of your institutional IRB approval memo
- Copy of your project proposal in recommended format at <https://www.usrds.org/for-researchers/standard-analysis-files/>
- Copy of this Data Use Agreement signed by your institutional official, PI, and all active participants.

Send ALL documents (including the research protocol) in PDF format and submit document to USRDS@USRDS.org.

Please note that any MODIFICATIONS or AMENDMENTS require a modification of the existing DUA or a new DUA if the aims of the project are changed substantially, regardless of whether the new aims or projects require additional files. In addition, a new IRB approval memo, new project proposal or copy of the original project proposal with additional analyses/extractions highlighted, and a new signed Data Use Agreement (bulleted items listed above) are required. Investigators may not have more than 5 active Data Use Agreements concurrently and may not request more than one data merge per DUA per year.

- On the final page is a checklist of all the elements required with your submission.
- Once you have all required signatures, please send documents to usrds@usrds.org
- A preliminary review will be conducted by personnel at the USRDS Coordinating Center before submitting the NIDDK for final approval
- Approvals can take 2-4 weeks