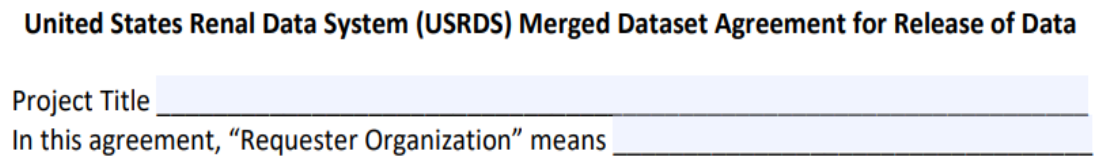
USRDS

United States Renal Data System

USRDS Merge Request 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 changes will require review by NIH and CMS an 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) Merged Dataset Agreement for Release of Data

Project Title _____

In this agreement, "Requester Organization" means _____

- All projects 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 years of data 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

Standard Analysis Files (SAFs) requested:

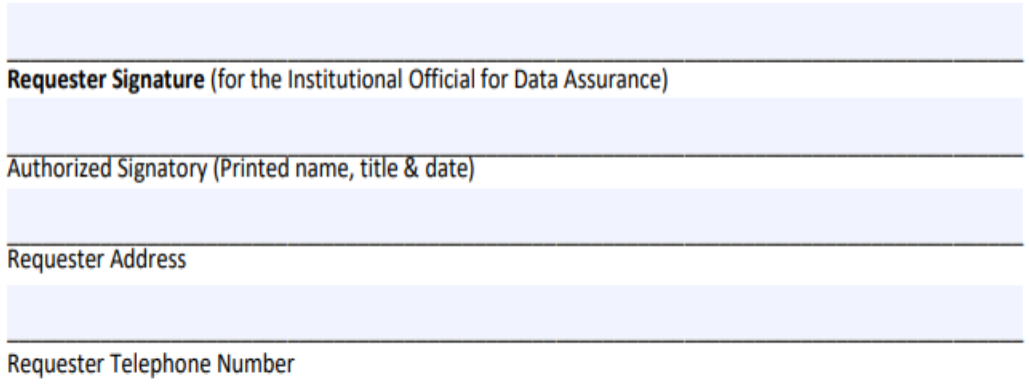
- ☐ Core
- ☐ Transplant
- ☐ Hospital
- ☐ CKD 5% Cohort Core
- ☐ CKD 5% Cohort Hospital
- ☐ CROWNWeb Clinical Data
- ☐ Dialysis Morbidity and Mortality Study (DMMS, 1993-1997)
- ☐ Comprehensive Dialysis Study (CDS, 2006)
- ☐ Clinical Performance Measures (CPM, 2000-2008)
- ☐ Case Mix Adequacy (CMA, 1990)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

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

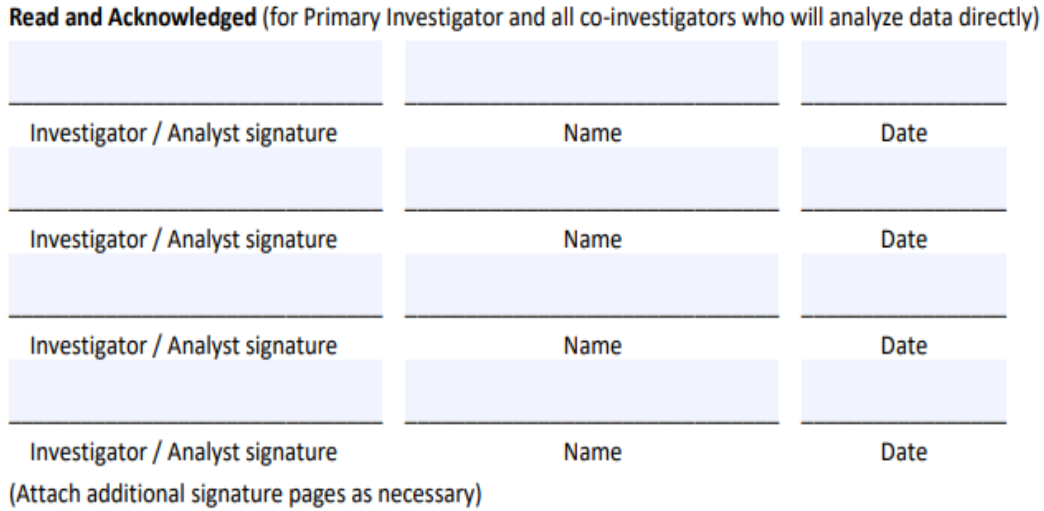
For the following SAFs, indicate the claim year(s) requested as well:

☐ 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



- 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 changes occur, 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)

- On the final page is a checklist of all of the elements required to submit with your proposal
- Once you have all the required signatures, completed proposal, and IRB approval letter, please send documents to usrds@usrds.org.
- A preliminary review will be conducted by personnel at the USRDS Coordinating Center before submitting to the NIDDK
- Approvals can take 3-4 weeks

Checklist:
DID YOU REMEMBER TO SEND:

☐ Signed copy of your institutional IRB approval memo

☐ Copy of your project proposal in recommended format at https://www.usrds.org/for-researchers/merged-data-requests/

☐ 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 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.