



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 and proposal.
- No changes to the language in items A-J will be accepted. Requesting these changes will require review by NIH and CMS, which will cause significant delays in the approval process.
- Requestor organization is the hospital, university or company at which the Principal Investigator (PI) works and will be housing the datasets. A second DUA may be required if the data will not be analyzed at the PI's site.
- If the data you are wish to merge is coming from a different site than the PI's, a second DUA may be required.

United States Renal Data System (USRDS) 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 projects.
- The files listed here are all cumulative files; no need to list dates on the form or in your proposal for these files.
- Active-Adipose Study and Transition of Care in CKD are special studies that contain data for limited years, please see the Researcher's Guide for more information.

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"/> CKD 5% Cohort Core |
| <input type="checkbox"/> Transplant | <input type="checkbox"/> CKD 5% Cohort Hospital |
| <input type="checkbox"/> 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 in the right hand column shown here if applicable. 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 available.
- Only the minimum data necessary to fulfill the objectives will be delivered and the proposal must justify the need for each of the datasets requested.

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

<input type="checkbox"/> Institutional Claims (pre-1989 through 2020)	
<input type="checkbox"/> Medicare Claims Clinical data (2011-2020)	
<input type="checkbox"/> Physician/Supplier Claims (1991–2020)	
<input type="checkbox"/> Part D Claims (2006–2020)	
<input type="checkbox"/> Pre-ESRD Institutional Claims (incident years 1995-2020)	
<input type="checkbox"/> Pre-ESRD Physician/Supplier Claims (incident years 1995-2020)	
<input type="checkbox"/> Pre-ESRD Part D Claims (incident years 2008-2020)	
<input type="checkbox"/> CKD 5% Institutional Claims (1992–2020)	
<input type="checkbox"/> CKD 5% Physician/Supplier Claims (1992–2020)	
<input type="checkbox"/> CKD 5% Part D Claims (2006–2020)	

- The crosswalks are necessary only if you are linking USRDS data to publicly-available data, they are not necessary to link the USRDS SAFs together.
- A special crosswalk will be produced for linkages, the crosswalks listed on the DUA are not necessary to link your data to the USRDS data.
- The Special Studies data include limited data for the years specified only. Additional justification is necessary in your proposal to receive these files. See the Researcher's Guide for information on these studies.

Crosswalks:

Provider Crosswalk

Physician Crosswalk

Special Studies:


Dialysis Morbidity and Mortality Study (DMMS, 1993-1997)

Clinical Performance Measures (CPM, 2000-2008)

Comprehensive Dialysis Study (CDS, 2006)

Case Mix Adequacy (CMA, 1990)

- The authorized signatory is a person from your legal/contracts department or the head of your specific department who has authority to sign DUAs/contracts and can attest to your data security.
- The signatory cannot be the PI or part of the project team.
- Remember to include *all* requested information for this individual.

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Signature of the Institutional Official for Data Assurance













Printed Name, Title & Date

Address

Telephone Number

- The PI must sign the DUA.
- Any individual touching the patient-level USRDS data must sign the DUA. This includes investigators, analysts, biostatisticians and IT individuals (if they will have access to the raw data).
- If personnel changes occur for your project, please contact the USRDS for instructions on updating your DUA accordingly.
- Additional signature pages can be found on the USRDS website.

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

Did you remember to include:

- Signed copy of your Institutional IRB approval
- Copy of your project proposal in recommended format (located: <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/standard-analysis-files> or <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/merged-data-requests>)
- Copy of this Data Use Agreement signed by your institutional official, PI and anyone who will be touching the USRDS data

Send ALL documents together in one email, in PDF or Word format, to USRDS@niddk.nih.gov *DocuSign will not be accepted.*

Please note that any MODIFICATIONS or AMENDMENTS to your proposal or project team require an amendment to your DUA. To amend your DUA, a new DUA form (same title, same requester, new data checked, all new signatures), a revised proposal (with changes highlighted), and an IRB approval (as necessary) is needed. Exceptions are when adding personnel, then only the DUA signature page is necessary. If changes to the proposal are significantly different from the original aims, a new DUA may be 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 data year.

- Once you have all the required signatures, please send all documents listed on page 4 via email to USRDS@niddk.nih.gov.
- A preliminary review will be conducted by USRDS staff before submitting to the NIDDK for final approval.
- Approvals can take up to 4 weeks to process.