USRDS

United States Renal Data System

USRDS DUA Form Instructions for a Standard Request

- 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.

United States Renal Data System (USRDS) 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 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.

Standard Analysis Files (SAFs) requested:

- ☐ Core
- ☐ Transplant
- ☐ Hospital
- ☐ CROWNWeb Clinical Data
- ☐ CKD 5% Cohort Core
- ☐ CKD 5% Cohort Hospital
- ☐ Active-Adipose Study (AAS, 2009-2013)
- ☐ Transition of Care in CKD (TCCKD)

- Please write in the years of claims requested in your research proposal in the right hand column.
- 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:

☐ Institutional Claims (pre-1989 through 2021)	_____
☐ Medicare Claims Clinical data (2011-2021)	_____
☐ Physician/Supplier Claims (1991–2021)	_____
☐ Part D Claims (2006–2021)	_____
☐ Pre-ESRD Institutional Claims (incident years 1995-2021)	_____
☐ Pre-ESRD Physician/Supplier Claims (incident years 1995-2021)	_____
☐ Pre-ESRD Part D Claims (incident years 2008-2021)	_____
☐ CKD 5% Institutional Claims (1992–2021)	_____
☐ CKD 5% Physician/Supplier Claims (1992–2021)	_____
☐ CKD 5% Part D Claims (2006–2021)	_____

- 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.
- 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)

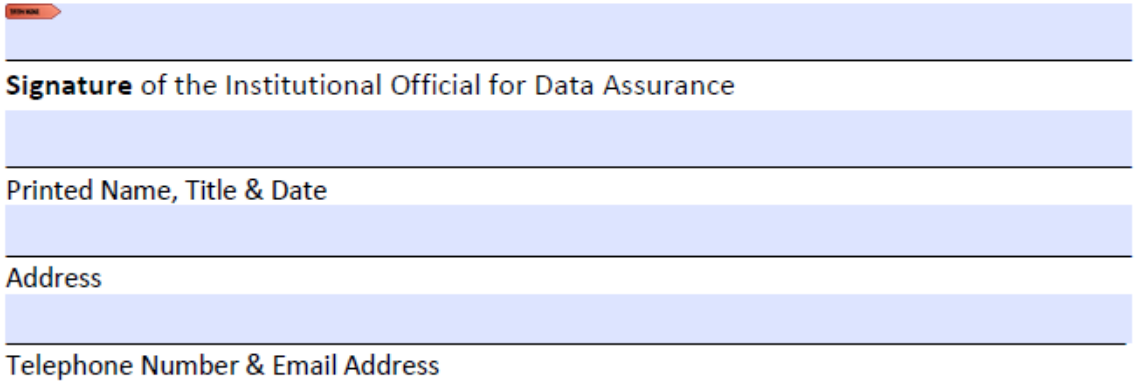
☐ Comprehensive Dialysis Study (CDS, 2006)

☐ Clinical Performance Measures (2000-2008)

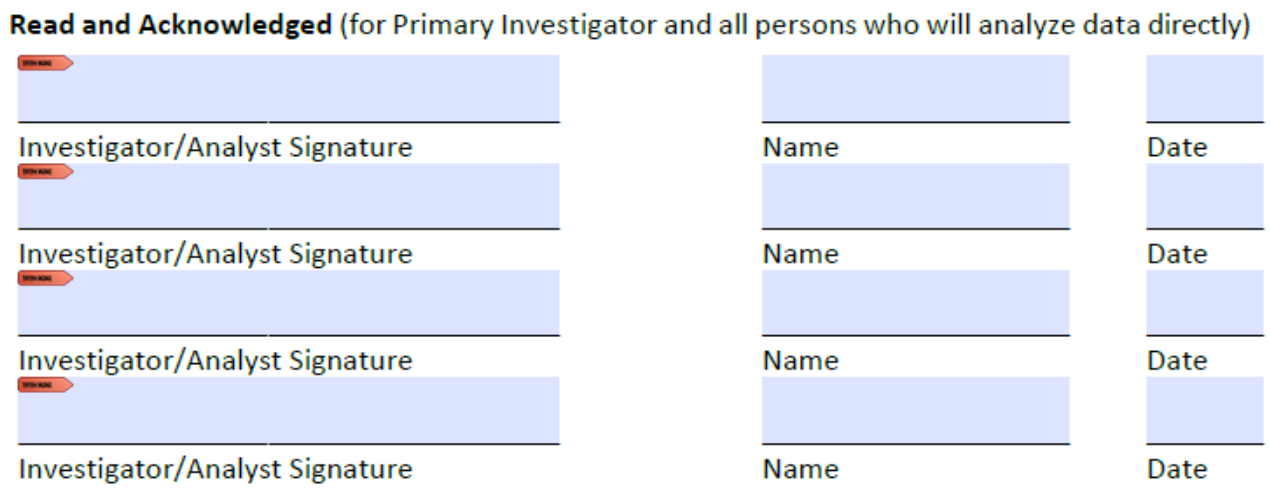
☐ Case Mix Adequacy (CMA, 1990)

☐ M Health Fairview data (2005-2021)

- The authorized signatory is a person from your legal/contracts department, IT head 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.



- 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 persons 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:

- A signed copy of you Institutional IRB approval
- A copy of your project proposal in recommended format located here: https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/standard-analysis-files for standard project and here: https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/merged-data-requests for merge projects
- A 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. Electronic signatures are accepted; *DocuSign or AdobeSign 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.