USRDS
United States Renal Data System

GENERAL INSTRUCTIONS FOR COMPLETING THE USRDS AGREEMENT FOR RELEASE OF DATA (DUA) FORM

to shorten the proposal review time, please read and follow these instructions before completing the DUA form.

Per the data provider (CMS), non-U.S. based researchers are prohibited from accessing identifiable CMS data. Therefore, USRDS is not permitted to send the USRDS SAFs outside of the United States (https://resdac.org/articles/cms-non-us-based-researcher-policy)

It is recommended you download the DUA and save on your computer/server before completing the document

Project Title

The project title should match the title on the IRB. The PI on the IRB should be the PI on the project.

Requester Organization

The Requester Organization is the University, Institution or Company where the Principal Investigator works. A second DUA may be required if the data will not be analyzed at the PI's site.

A-M

Terms of the DUA. No edits are allowed to the terms.

N

Standard Analysis Files: Check the boxes of the datasets you require for your project. Because the data provider requires the release of the minimum amount of data necessary to fulfill the project, you will need to justify the use of each of these datasets in the proposal. Justifications should be specific to the datasets and demonstrate to the reviewer that you understand the contents of the dataset. Information on what is contained within each dataset can be found in the Researcher's Guide and Appendices found on the USRDS website

Claims SAFs: Check the boxes of the claims datasets you require for your project. Include the years requested on the lines at the right. The lines must include years; 'all years', 'present', 'all available' are not accepted. Only years listed on the DUA are available for request; approvals are not granted for years not yet released. Similar to the above datasets, each checked dataset must be justified within the proposal. Information on what is contained within each claims dataset can be found in the Researcher's Guide and Appendices found on the USRDS website

Crosswalks: Crosswalks are only needed if your project requires <u>you</u> to link the USRDS data to a publicly-available dataset, such as the Dialysis Facility Compare data, etc. These crosswalks are not necessary to link the various USRDS datasets together, nor necessary for a Merge project. The crosswalk for a Merge project is automatically sent to the researcher.

The Provider crosswalk includes the CMS control number to the USRDS provider number. The Physician crosswalk includes the NPI to USRDS physician number.

USRDS
United States Renal Data System

Signature of the Institutional Official for Data Assurance

The signatory should be someone within your University, Institution or Company with the authority to sign contracts or agreements, and they must be able to attest to security of the USRDS data and cannot be part of the project team. Please make sure to complete all the requested information, including title, address and phone number. Appropriate administrative, technical, procedural, and physical safeguards are needed to protect the confidentiality of the Data and to prevent unauthorized access. Safeguards to limit access control, usage restrictions, connection requirements such as cryptography connected to managed network access control points, a continuous monitoring program that manages identified vulnerabilities, remediation and ongoing security assessments, policies to prevent users from installing non-approved software and for identification/authentication of users, and information systems that use FIPS* 140-2 validated cryptographic modules for data, both in-transit and at rest.

Read and Acknowledged

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).

USRDS Contracting Officer Representative

This space will be signed by the COR once your project has been submitted by the USRDS Coordinating Center and reviewed. The signed DUA will be returned to you along with your requested datasets.

Changes to your project team should be submitted to the USRDS. Additions located at your institute should be submitted to your IRB and can be added to your DUA via an additional signature page found on the DUA website page. Adding individuals at other locations can be done, please contact the USRDS (USRDS@niddk.nih.gov) for more information. If the PI relocates, the DUA must be transferred to another individual at the contracting institution. Please contact the USRDS for information on this process. If individuals working with the USRDS data relocate outside of the US, their access to the USRDS data must be stopped and they must be removed from the DUA.

All documents (DUA, Proposal, IRB approval) should be sent together to the USRDS (USRDS@niddk.nih.gov) in PDF or Word format.

The PI must be included on all correspondence.

The USRDS will return approvals to the PI; the PI is responsible for distributing documents within their institution as necessary.

Any changes to the requested data will require obtaining new signatures on the form. It is strongly encouraged that you submit your proposal and DUA documents for initial review before obtaining institutional signatures.

*Federal Information Processing Standards https://www.nist.gov/standardsgov/compliance-faqs-federal-information-processing-standards-fips

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

Project Title

_____

In this agreement, “Requester Organization” means

_____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center, will provide the Requester data extracted from the USRDS research database (the “Data”), via download, which constitutes a Limited Dataset within the meaning of the HIPAA privacy regulations.

B. The sole purpose of providing the Data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Requester.

C. The Requester shall not use the Data to identify individual beneficiaries or individual providers on the files.

D. The Requester shall not combine or link the Data provided with any other collection or source of information that may contain information specific to individuals on the files, except where a waiver of authorization has been approved by the Requester’s IRB/Privacy Board and NIDDK.

E. The Requester shall not use the Data for purposes that are not related to biomedical research, cost-effectiveness, economic and/or other epidemiological research. Purposes for which the Data may not be used include, but are not limited to,

   - the identification and targeting of under- or over-served health service markets primarily for commercial benefit
   - the obtaining of information about providers or facilities for commercial benefit
   - insurance purposes such as redlining areas deemed to offer bad health insurance risks
   - adverse selection (e.g., identifying patients with high risk diagnoses).

   Any use of the Data for research not in the original proposal must be approved by the USRDS Contracting Officer Representative (COR).

F. The Requester shall not publish or otherwise disclose the Data in the files to any

person or organization unless the Data have been aggregated (that is, combined into groupings of Data such that the Data are no longer specific to any individuals within each grouping), and no cells (aggregates of Data) contain information on fewer than eleven individuals or fewer than five providers or facilities, or allow for calculation of cells with fewer than eleven individuals. The Requester shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred. However, the Requester may release Data to a contractor for purposes of data processing or storage if (1) the Requester specified in the research plan submitted to the USRDS Contracting Officer Representative (COR) that Data would be released to the particular contractor, or the Requester has obtained written authorization from the COR to release the Data to such contractor, and (2) the contractor has signed a data release agreement with the COR.

G. A copy of any aggregation of Data intended for publication shall be submitted to the USRDS for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The COR must respond within 30 days.

H. All publications using the USRDS data must contain this 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 U.S. government.' Publications must also include a citation for the USRDS data.

I. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Requester to protect the confidentiality of the Data and to prevent unauthorized access to it. Information systems must use FIPS 140-2 validated cryptographic modules for data in-transit and at rest. Other safeguards include, but are not limited to, safeguards to limit access control, usage restrictions, connection requirements such as cryptography connected to managed network access control points, a continuous monitoring program that manages identified vulnerabilities, remediation and ongoing security assessments, policies to prevent users from installing non-approved software and policies for identification/authentication of users.

☐ The Requesting Organization attests that data are encrypted both in-transit and at rest utilizing the latest FIPS 140-2 compliance requirements

J. No copies or derivatives shall be made of the Data in these files except as necessary

for the purpose authorized in this agreement. The Requester shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the COR. The USRDS Data files covered in this data use agreement (DUA) may be retained by the Requester until the date specified by the COR in the approval letter, at which time the Requester may request renewal of this data use agreement to extend the retention period to comply with legal or institutional recordkeeping requirements or to maintain the integrity of the research or research publications. If at any time during the data retention period the DUA between USRDS and CMS is canceled, the Requester will be contacted to destroy the files in their possession. At the completion of the activities in the research plan, the file(s) and any derivative files and copies shall be destroyed. At that time, the Requester will inform the USRDS and the COR in writing that the files have been destroyed and complete the USRDS Data Destruction Certificate.

K. The USRDS requires IRB review of research proposals. The IRB must review the proposal for a waiver of HIPAA authorization and a waiver of informed consent.

☐ The IRB has exempted the study from review or granted a waiver of informed consent

☐ The IRB has granted a HIPAA waiver (by indicating a waiver of the Privacy Rule requirements, waiver of release of information authorization, or referencing the specific statute)

L. For the purpose of inspecting security procedures and arrangements, authorized representatives of the NIDDK and/or of CMS will, upon request, be granted access to premises where the Data are kept.

M. Per the data provider (CMS), non-U.S. based researchers are prohibited from receiving or from accessing the USRDS Standard Analysis Files through any means, including Virtual Private Network (VPN). For the full policy, see https://resdac.org/articles/cms-non-us-based-researcher-policy

Continued on next page

N. The following USRDS Data is/are covered under this Agreement.

Standard Analysis Files (SAFs) requested:

☐ Core
☐ Transplant
☐ Hospital
☐ CROWNWeb Clinical Data
☐ CKD 5% Cohort Core
☐ CKD 5% Cohort Hospital
☐ M Health Fairview data (2005-2021)

For the following SAFs, indicate the claim year(s) requested on the line:

☐Institutional Claims (pre-1989 through 2022) _____

☐Medicare Claims Clinical data (2011-2022) _____

☐Physician/Supplier Claims (1991–2022) _____

☐Part D Claims (2006–2022) _____

☐Pre-ESRD Institutional Claims (incident years 1995-2022) _____

☐Pre-ESRD Physician/Supplier Claims (incident years 1995-2022)_____

☐Pre-ESRD Part D Claims (incident years 2008-2022) _____

☐CKD 5% Institutional Claims (1992–2022) _____

☐CKD 5% Physician/Supplier Claims (1992–2022) _____

☐CKD 5% Part D Claims (2006–2022) _____

Crosswalks:

☐ Provider Crosswalk
☐ Physician Crosswalk

_____

Signature of the Institutional Official for Data Assurance

_____

Printed Name, Title & Date

_____

Address

_____

Telephone Number & Email Address

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
_____	_____	_____
Investigator/Analyst Signature	Name	Date

(Attach additional signature pages as necessary, they can be found on the USRDS website)

Authorizing NIDDK Official:

_____
Authorizing NIDDK Official Signature

The Expiration date of this DUA is: _____

Did you remember to include:

- Your 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 projects 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 for data assurance, PI and anyone who will be touching the USRDS data

Electronic signatures are accepted.

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

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 located at your institution, 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.