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 title should be focused. It 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. The Requesting Organization is responsible for the correct storage and use of the USRDS data. A second DUA may be required if the data will not be analyzed at the PI's site.

A-O

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

P

Standard Analysis Files: Check the boxes of the datasets you require for your project. Because the data provider requires the release of only 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 you 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.

Signature of the Requesting Organization Institutional Official for Data Stewardship

The signatory must be someone within the Requesting Organization (your University, Institution or Company) with the authority to sign contracts or agreements, they must be able to attest to the safety and security of the USRDS data and cannot be part of the project team. By signing this agreement, they accept responsibilities for compliance with all terms and conditions therein.

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 USRDS 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. It is required that your information systems 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 (having access to the raw data). Only the minimum number of individuals necessary to complete the project should be included in the project team and sign the DUA.

Authorizing NIDDK Official

This space will be signed by the Authorizing NIDDK Official 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.

IRB documentation is necessary to obtain approval to receive the USRDS data. Your IRB may approve your study, or it may exempt it from review. Either outcome is acceptable. Your IRB must approve a waiver of consent (this waiver is implied if your IRB exempts your study from review). Your IRB should also review your study with regard to the requirements of the HIPAA Privacy Rule and approve a waiver of authorization for disclosure of information. Both boxes in section M of the DUA must be checked. A determination of "Not Human Subjects Research (NHSR)" will not be accepted. The USRDS SAFs are neither publicly available nor completely de-identified.

Revisions to your project must be submitted to the USRDS Coordinating Center.

Requesting a new year of data requires:

- New DUA form (same title, same Requester Organization, datasets checked and year listed, all new signatures of all individuals accessing the USRDS data)
- Progress report (found on the USRDS website)
- Revised proposal with the new data added and highlighted. Please indicate if there are any

personnel changes by adding new members and crossing off those who are no longer part of the team

- IRB approval/documentation as required

Changes to your project team should be submitted to the USRDS. This requires:

- IRB approval/documentation of acknowledgement of new project team members as required
- New DUA form (same title, same Requesting Organization, all new signatures including the new team members)
- Revised proposal with the new team members' contact information added and highlighted. Please indicate if previously named team members are no longer working on the project and can be removed from the DUA.

Extensions:
DUAs are approved for a standard length of time; extensions to the expiration date may be granted in exceptional circumstances. The PI must submit an email to the USRDS requesting an extension including a reason why the extension is necessary along with the required progress report found on the USRDS website. An extension request should not be sent until November of the year of expiration.

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 Requesting Organization. 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. Access to the USRDS data outside of the US is strictly forbidden. This includes US researchers who are temporarily located outside of the US.

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.

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) Merged 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. Prior to receiving the USRDS data, the Requester will provide USRDS with a list of personally identifiable information (PII) so the USRDS can report which of the Requester's subjects are in the USRDS end-stage renal disease (ESRD) data. The USRDS shall not use or disclose the Requester's data for any purpose other than to create the report. In the event the Requester's data is used or disclosed for any purpose other than that covered by this agreement, the USRDS will notify the Requester immediately and agree to work with the Requester to address the use and disclosure. The USRDS will destroy the Requester's dataset within one year after the linkage is complete.

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. ***Research*** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46) directed toward a fuller scientific knowledge or understanding of the subject studied.

C. Data use agreements are for the approved proposal only, use of the Data for other purposes or aims is not allowed and may result in corrective actions.

D. The Requesting Organization shall contractually bind any investigators, analysts, biostatisticians, co-investigators, and/or collaborators to the terms and conditions of this Agreement. The Requesting Organization further agrees that within the Requesting Organization access to the Data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this proposal.

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

F. 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.

G. The Requester shall not use the Data for purposes that are not related to research as defined in Section B. 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
- institutional quality assurance or quality control
- 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 Authorizing NIDDK Official.

H. 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 allow for calculation of cells with fewer than eleven individuals. The Requester shall not publish or otherwise disclose the Data in the files to any person or organization on fewer than five providers or facilities or Data from which individual providers or facilities 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 Authorizing NIDDK Official that Data would be released to the particular contractor, and (2) the contractor has signed a data release agreement submitted with the project proposal.

I. 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 NIDDK reviewer has 30 days to respond. Failure to comply with the terms of data privacy detailed in Section H will result in corrective action and may jeopardize the Requester Organization from obtaining USRDS data for future projects.

J. 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.

K. Appropriate administrative, technical, procedural, and physical safeguards shall be

established by the Requester Organization to protect the confidentiality of the Data and to prevent unauthorized access to it. Information systems must use FIPS 140-2 or above validated cryptographic modules for data in-transit and at rest or NIST 800-171 compliant security. Other security measures 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 or utilizes NIST 800-171 compliant security.

L. 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 NIDDK. The USRDS Data files covered in this data use agreement (DUA) may be retained by the Requester until the date specified by NIDDK 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 expiration of the DUA, the file(s) and any derivative files and copies shall be destroyed in accordance with NIST SP 800-88. At that time, the Requester will inform the USRDS and NIDDK in writing that the files have been destroyed and complete the USRDS Data Destruction Certificate.

M. 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, granted a waiver of informed consent, or approved a consent form that participants must sign

☐ 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)

N. 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.

O. 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

P. 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:

☐ ESRD Institutional Claims (1999 through 2023) _____

☐ Medicare Claims Clinical data (2011-2023) _____

☐ ESRD Physician/Supplier Claims (1999–2023) _____

☐ ESRD Part D Claims (2006–2023) _____

☐ Pre-ESRD Institutional Claims (incident yrs 1999-2023) _____

☐ Pre-ESRD Physician/Supplier Claims (incident yrs 1999-2023) _____

☐ Pre-ESRD Part D Claims (incident years 2008-2023) _____

☐ CKD 5% Institutional Claims (1999–2023) _____

☐ CKD 5% Physician/Supplier Claims (1999–2023) _____

☐ CKD 5% Part D Claims (2006–2023) _____

Crosswalks:

☐ Provider Crosswalk

☐ Physician Crosswalk

_____

Signature of the Requesting Organization Institutional Official for Data Stewardship

_____

Printed Name, Title & Date

_____

Address

_____

Telephone Number & Email Address

Read and Acknowledged (for Principal 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 documentation
- 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 Stewardship, 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 changes to your proposal or project team require an amendment to your DUA. Instructions on amendments can be found in the DUA instructions.

A progress report will be required for an extension request or a request for the new year of data. The report document can be found on the USRDS website.

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.