**GENERAL INSTRUCTIONS FOR COMPLETING THE USRDS STANDARD PROPOSAL**

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

**There are at least three documents needed for a request: Proposal, Data Use Agreement (DUA), IRB review. Incomplete submissions will not be processed**

1. Research title

The title should match the title on the IRB and USRDS DUA. The PI on the IRB should be the PI on the project.

1. Submission date

Date of the final submission to the USRDS (after preliminary review)

1. PI name

Name of the Principal Investigator for the project. This should be the same person as the PI on the project IRB.

1. Funding Source (if NIH, provide grant number)

Name of the funding source. If NIH, please indicate which department/division and include the grant number. If no source, put N/A

1. USRDS DUA # (if submission is an amendment, otherwise N/A)

The USRDS assigns a DUA number upon approval of the project. If this is a first submission (original), then put N/A. If this is an amendment, put the DUA number assigned on the original approval letter.

1. Background information

In three to four paragraphs, provide a comprehensive description of the background and reason(s) for your research.

1. Study design
2. Objectives

Clearly list your project objectives or aims.

1. Hypothesis(es)

Clearly state the hypothesis of your objectives or aims.

1. Analytical methods

Include detailed information on your design, cohort(s), methods, and how the USRDS data will be used to complete your project. The methods should support the need for the requested datasets. Only the minimum data necessary to complete the objectives/aims will be approved. If there are specific reasons why a dataset is needed or certain years of claims is necessary, include this in your design. Any information to support the necessity of your requested datasets will help the reviewer approve them.

1. Data being requested
2. List of Standard Analytical Files needed (Information on the specific datasets and the variables found within each can be found in the Researcher’s Guide and Appendices located here: <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/researchers-guide>
	* **Please specify years required where applicable**

Only claims have years associated with them (as listed on the DUA). Only years listed on the DUA are available, we do not accept submissions for data years not yet released. Be sure to write the years for each dataset requested behind the name (e.g. Institutional claims (2018-2022))

* + **Include a specific justification for each dataset checked on the DUA (bulleted list)**

Each *dataset selected* on the DUA must be listed and justified (e.g. Core, Hospital, ESRD Institutional). *Do not list and justify individual files or variables found in the datasets.* Be specific (e.g. what information will be obtained from the ESRD Physician/Supplier claims that is not available in the ESRD Institutional claims). Only the minimum data necessary to complete your project objectives will be approved.

If you are requesting data prior to 2000 you must include additional justification why these years are necessary for your research.

We do not accept requests for data years that has not yet been released. The DUA specifies the years available for request.

1. Description of data security

Include relevant, detailed information on your institutional IT security measures to protect the safety and confidentiality of the data. Include details such as:

* + What is the physical security of the computers or servers (locked building, locked room);
	+ Are there system controls to limit access to the data and connection requirements;
	+ Are there individual logins and identification/authentication of users;
	+ Does the system use FIPS 140-2 modules for data in-transit and at rest;

Are any of your study team located at a different institution and will be accessing the data on your servers? Include information on how this access will happen.

1. Include this exact statement in your proposal

 'The USRDS data will be destroyed at the end of the project'.

The USRDS expiration dates are standard, however, if the expiration date is near and you will not be able to complete your project in time, you can request an extension. This is done by the PI submitting an email to the USRDS requesting an extension to your DUA (include DUA number) with a reason why the extension is necessary.

1. Contact information for principal investigator, analysts & anyone accessing the data. We do not accept personal email addresses such as yahoo, gmail, msn, etc. Email addresses must be related to your institution. Contact information necessary includes
	* Name
	* Affiliation
	* Business address
	* Business phone number
	* Email address

If personnel are housed at different institution, or not affiliated with your institution, be sure that is clearly indicated. If personnel at a different institution will be accessing the patient-level USRDS data they will need an IRB approval. An additional DUA may be required depending on how these individuals are accessing the data.

Other documents required with your submission:

**IRB approval letter/documentation or waiver**

The USRDS data is a limited dataset of Medicare data. Information on privacy practices for Medicare data can be found here: <https://www.medicare.gov/basics/reporting-medicare-fraud-and-abuse/privacy-practices-original-medicare>

Your IRB may approve your study, or it may exempt it from review. Either outcome is acceptable.

Your IRB will review the study with regard to the requirements of the Common Rule:

* The Common Rule is a federal policy that covers the protection of human subjects in research.
* The Common Rule requires that researchers obtain informed consent from each human subject for their participation in the research, OR
* If certain conditions are met, the IRB may waive the Common Rule requirement to obtain informed consent. The waiver is also implied if the IRB exempts the study from review (or exempts the study from the Common Rule).

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.

IRB documentation format

There isn’t one specific form or format, but there are some basic IRB documentation requirements.

* + Name of the IRB and contact information (preferably via letterhead)
	+ Date of review or approval and expiration date (some exemptions may not expire)
	+ Study title: Must be the exact same study title as on your DUA and proposal
	+ Principal Investigator (PI) name: Must be the same as the PI name on your proposal
	+ Determination of IRB approval or exemption, and brief explanation
	+ Name/signature of the authorized IRB representative

For more information on IRB requirements can be found here: <https://resdac.org/search/node?keys=IRB>

If any of your study team is located at a different institution, they must provide an IRB approval from their institution for the research project, or your approving-IRB must provide a letter of agreement for reliance.

**A signed USRDS Agreement for Release of Data**

The blank DUA can be found here: <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/for-researchers/standard-analysis-files>

The DUA form includes instructions for completing.

Email your request to USRDS@niddk.nih.gov

* Attach all required documents, incomplete submissions will not be processed
* Include the PI on all email correspondence
* The USRDS accepts electronic signatures on the documents, however, they do not accept DocuSign or AdobeSign submissions, documents must be emailed in PDF or Word
* Indicate “USRDS DUA Request” in the subject line of the e-mail

Outline for Standard Research Proposals Using USRDS Data

1. Research title
2. Submission date
3. PI name
4. Funding Source (if NIH, provide grant number)
5. USRDS DUA # (if submission is an amendment, otherwise N/A)
6. Background information
7. Study design
8. Objective(s)
9. Hypothesis(es)
10. Analytical methods – Include how the USRDS data will be used to fulfill your objectives
11. Data being requested
12. List the datasets requested for your project (selected on the DUA). **Please specify years required where applicable and include a specific justification for each dataset selected on the DUA.** Note, if you are requesting data prior to 2000 you must include additional justification why these years are necessary for your research.
13. Description of data security. Please read instructions and the DUA for more information on security measures.
14. Include this exact statement in your proposal

 'The USRDS data will be destroyed at the end of the project'.

1. Contact information for principal investigator, analysts & anyone accessing the data. We do not accept personal email addresses such as yahoo, gmail, msn etc. Email addresses must be related to your institution:
	* Name
	* Affiliation
	* Business address
	* Business phone number
	* Email address

**Be sure to submit along with your proposal**

* IRB approval letter/documentation
* A signed USRDS Agreement for Release of Data