USRDS
UNITED STATES RENAL DATA SYSTEM

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 or on DVDs or other media type, which constitutes a Limited Dataset within the meaning of the HIPAA privacy regulations. Prior to receiving USRDS data, the Requester will provide USRDS with a list of personally identifiable information (PII) so USRDS can report which of the Requester's subjects are in the USRDS end-stage renal disease (ESRD) data.
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. USRDS shall not use or disclose the Requester's data for any purpose other than to create the Data extracted from the USRDS database. In the event that the Requester's data is used or disclosed for any purpose other than that covered by this agreement, USRDS will notify the Requester immediately and agree to work with Requester to address the use or disclosure. The USRDS will destroy the Requester's dataset one year after the linkage is complete unless otherwise specified by the Requester in the research proposal.
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 Project Officer (PO).
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. 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 Project Officer that Data would be released to the particular contractor, or the Requester has obtained written authorization from the PO to release the Data to such contractor, and (2) the contractor has signed a data release agreement with the PO.

G. A copy of any aggregation of Data intended for publication shall be submitted to the PO 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 PO must respond within 30 days.

   The Approval Request Checklist may be found at:
   https://www.usrds.org/2018/appx/USRDS_Manuscript_Approval_Request_Checklist.pdf

H. 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. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information Resources, which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. 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 PO. The USRDS Data files covered in this data use agreement (DUA) may be retained by the Requester until the date specified by the PO in the approval letter, at which time 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 PO in writing that the files have been destroyed.

J. 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.

K. The following USRDS Data file(s) is/are covered under this Agreement.

Standard Analysis Files (SAFs) requested:

☐ Core
☐ Transplant
☐ Hospital
☐ CKD 5% Cohort Core
☐ CKD 5% Cohort Hospital
☐ CROWNWeb Clinical Data
☐ Dialysis Morbidity and Mortality Study (DMMS)
☐ Comprehensive Dialysis Study (CDS)
☐ Clinical Performance Measures (CPM)
☐ Case Mix Adequacy (CMA)
☐ Active-Adipose Study (AAS)
☐ Transition of Care in CKD (TCCKD)

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

☐ Institutional Claims (pre-1989 through 2016 available) _____
☐ Medicare Claims Clinical Data (2011-2016) _____
☐ Physician/Supplier Claims (1991–2016 available) _____
☐ Part D (2006–2016 available) _____
☐ Pre-ESRD Institutional Claims (incident years 1995-2016) _____
☐ Pre-ESRD Physician/Supplier Claims (incident years 1995-2016) _____
☐ Pre-ESRD Part D (incident years 2008-2016) _____
☐ CKD 5% Institutional Claims (1992–2016 available) _____
☐ CKD 5% Physician/Supplier Claims (1992–2016 available) _____
☐ CKD 5% Part D (2006–2016 available) _____

Crosswalks:

☐ Provider Crosswalk ☐ Physician Crosswalk ☐ UNOS Crosswalk*

**UNOS – United Network for Organ Sharing. Requester must provide proof of UNOS data approval & patient identifiers to link with USRDSID*

IMPORTANT! Specify:

☐Data ONLY on matched patients ***OR***

☐Complete SAFs, including matched and unmatched patients

_____

Requester Signature (for the Institutional Official for Data Assurance)

_____

Authorized Signatory (name, title & date)

_____

Requester Address

_____

Requester Telephone Number

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

(attach additional signature pages as necessary)

USRDS Project Officer: Kevin C. Abbott, MD, NIDDK, NIH, Kevin.abbott@nih.gov

_____

USRDS Project Officer Signature Date

Checklist:
DID YOU REMEMBER TO SEND:

☐ Signed copy of your institutional IRB approval memo

☐ Copy of your project proposal in recommended format at http://www.usrds.org/2018/appx/3/Outline_for_Research_Proposals_Using_Merged_USRDS_Data.pdf

☐ Copy of this Data Use Agreement signed by your institutional official, PI, and all active participants.

Please note that any MODIFICATIONS or AMENDMENTS, regardless of whether they require additional files, require a new IRB approval memo, copy of the original project proposal with additional analyses/extractions highlighted, and a new signed Data Use Agreement (bulleted items listed above).

Please send ALL documents (including the research protocol) in PDF format AND consolidate all files into a single PDF file (using the "PDF Portfolio" feature in Adobe) when sending to the NIDDK.

05/01/2019 revision