Data Use Agreement

for bona fide research & analysis

Project number (SRTR use only): 10178
Date: 3/282024

Pursuant to a contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS), through the Chronic Disease Research Group (CDRG) of the Hennepin Healthcare Research Institute (HHRI), with offices at 914 S. 8th Street, Suite S4.100, Minneapolis, Minnesota 55404, the Scientific Registry of Transplant Recipients (SRTR) Contractor will provide the organization identified below (Recipient) with patient-level data (but not patient-identified data unless authorized in writing as described below). The data extracted from the SRTR research database is maintained by HHRI solely for the use identified below. Patient-identified data may only be made available when approved by the SRTR Contracting Officer's Representative (COR). The recipient of released data will abide by the terms stated in the Agreement Clauses.

Recipient name Xing Song, Ph.D.

Institution University of Missouri Phone (573) 882-1352

Mailing address (include city, state and zip code)
1 Hospital Dr. Columbia, MO 65212 United States

Contact name Xing Song, Ph.D.

Phone (573) 882-1352 Email xsm7f@umsystem.edu

Check all that apply: ■ Standard analysis files (SAF) ☐ LSAM ☐ TSAM ☐ KPSAM ■ Additional variables

Description of data to be delivered SAF. Additionally we are requesting Datavant privacy protecting tokens with a PPT to encrypted OPTN ID crosswalk.

Date of delivery 4/1/2024 Format SAS

(SAF available only in SAS)

Description of patient-identified information needed (if any) for research proposal and why it is needed (patient-identified data must be approved by the SRTR COR)

We are requesting a privacy protecting token (PPT) from Datavant linked to OPTN encrypted ID cross walk. This will be used to link to a limited data set from PCORnet.

Purpose for which recipient intends to use the data (**attach research plan**):

Development of machine learning models to improve post transplant immunosuppression models using novel data sets as outlined in the analytic plan

Assurance of confidentiality of data (**attach security plan**; see item 10 of attachment):

All data will be stored and accessed through a highly secure data center at the University of Missouri as outlined in the security plan

Agreement includes this document, attachment, research plan and security plan.

AGREED AND ACCEPTED:

Xing Song, Ph.D.

Recipient typed name and title

Xing Song

Digitally signed by Xing Song
Date: 2024.03.29 09:21:45 -05'00'

Recipient signature and date

Shannon M. Dunne -S

Digitally signed by Shannon M. Dunne -S
Date: 2024.04.29 11:07:09 -04'00'

Shannon Dunne, JD, SRTR Contracting Officer's Representative, HRSA, HHS*

Bryn Thompson

Digitally signed by Bryn Thompson
Date: 2024.04.29 16:10:22 -05'00'

Hennepin Healthcare Research Institute Representative (signature and title)

* Required only when patient-identified data are obtained. Approval by the COR hereby provides exception to clause 2 of this Agreement which prohibits use of the Data (as defined in the Agreement) to identify individuals and further prohibits linking or combining the Data with other information so as to identify individuals.

Attachment – Agreement clauses

The Recipient acknowledges, agrees, and represents that, unless otherwise expressly permitted in writing by the SRTR COR:

Rights in data

1. The rights to the released Data are retained by HHS/HRSA and the SRTR Contractor.

Access to patient-identified data

2. Patient-identified data may be made available only after documentation of Institutional Review Board (IRB) approval or exemption is presented for the proposed study. The SRTR COR must approve the proposed study. If approved and justified, these may be linked to other data sets, consistent with the research plan.

Use of data

3. The Recipient acknowledges responsibility for submitting a research plan to the Recipient's IRB for approval or exemption determination for the research project using the released Data.

4. Upon request, the Recipient will provide the SRTR with a progress report on the study and a description of how compliance with the terms of this agreement has been maintained.

5. The Recipient shall not use the Data to identify individuals, and will not link or combine the Data with other patient-level information, unless approved by the SRTR COR in writing.

6. The Recipient shall use the Data solely for bona fide research/analysis described in the Purposes set forth above, and specifically shall not use the Data for any commercial purpose that could have a negative impact on patient welfare, such as offering, denying, or allocating insurance; and adverse selection (e.g., identifying patients with high-risk diagnoses).

7. The Recipient shall not make copies of the Data, and shall not sell information derived from the Data.

8. However, the Recipient may release data to a subcontractor for purposes of data processing or storage if (1) the Recipient specifies in the research plan submitted to the COR that data would be released to the particular subcontractor, or the Recipient has obtained written authorization from the COR to release the data to such subcontractor, and (2) the subcontractor has signed a data use agreement with the COR.

9. Before submitting an abstract, manuscript, or other aggregation data to another party for presentation or publication, the Recipient must submit it to the SRTR and COR for review to ensure compliance with the terms of this agreement regarding confidentiality. The COR shall respond within 30 days. If the abstract, manuscript, or data aggregation does not reflect compliance with the terms of this agreement, the Recipient will revise and resubmit to the SRTR and COR. Upon publication, the Recipient shall provide a copy of the final work and a complete citation to the SRTR and COR.

10. Only those employees who have a "need to know" shall access the Data, and all such employees shall be advised of the terms of this Agreement and the restrictions upon use and disclosure. The names of all such employees and collaborators shall be provided with the application and shall be supplemented if any are added or subtracted after the application is approved.

11. The Recipient shall keep an accurate written account of all authorized copies of the Data, and of work product derived from the Data, and will furnish such written logs upon request to the COR and/or to the SRTR.

12. All publications using the released Data must contain the standard disclaimer, "The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). 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 of or interpretation by the SRTR or the U.S. Government."

13. All publications using the released Data must contain a statement confirming that the study was submitted to a functioning IRB for review and approval. The IRB determination status must be indicated in the text of any manuscript using the released Data.

14. All publications using the released Data must contain this standard statement within the methods section of the publication, "This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors."

Data confidentiality procedures

15. The Recipient acknowledges that the Data are private and confidential, and that unauthorized use is a violation of the terms of this Agreement and may subject the Recipient and its employees to appropriate sanctions found in #22 of this document.

16. The Recipient has in place, and shall maintain during the term of this Agreement, administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the Data and to prevent unauthorized access and use. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

Term of agreement and destruction of data upon completion of research project

17. This Agreement shall begin on the date the completed agreement was received and shall continue until the completion of the research project, with a period of permitted use of three years. The duration of this Agreement may be extended beyond the three years, at which time; the Recipient shall complete a Data Status Confirmation form. This form shall be completed annually until the Recipient no longer requires use of the Data at which time; the Recipient shall return the Data, or shall certify in writing the deletion and destruction of all copies of the Data and all authorized work product derived from the Data, including the certification that all archival and backup copies of electronic storage media containing the Data, will not be accessed unless the Recipient has presented adequate justification of a research or health nature for retaining such information.

18. The Agreement may be terminated by the Recipient at any time for any reason (such as completion of research project, decision by the IRB, etc.) upon 30 days written notice prior to the end of the Agreement period. Upon notice of early termination by the Recipient, the Recipient shall return the data as specified in clause 17.

19. The Recipient shall permit authorized representatives of the COR and SRTR access to premises where Data are kept for the purpose of inspecting security procedures and compliance with the terms of this Agreement.

Approval of modifications to submitted research plan

20. If there are changes in the research plan originally submitted as part of this Agreement, the Recipient must provide to COR and SRTR a memorandum describing the changes in advance of the revisions. These revisions will be considered as amendments to this Agreement and may not be implemented without approval in writing by the COR.

21. A change in employer of the Recipient requires the execution of a new Agreement. This must be approved by the COR in writing before data may be accessed at the new place of employment.

Violation of this agreement

22. In the event that HRSA or the SRTR becomes aware of violations of the terms of this Agreement or use of the Data or any part of it that is not authorized under this Agreement or is contrary to applicable laws, the SRTR and/or HHS/HRSA may notify the Recipient to end the violation and cure the breach. The SRTR also will notify HHS/HRSA of the violation and may (1) terminate this Agreement immediately and without further notice; and/or (2) disqualify (in whole or in part) the Recipient at fault and/or any authorized parties from receiving SRTR Data in the future. The Federal government may also pursue further sanctions under 45 CFR Part 46 or other applicable laws.