DMG REGISTRY DATA REQUEST FORM - DATA LINKAGE

Address each numbered point concisely. You may use additional pages, if needed. Please e-mail completed materials to dmgdata@unos.org

1. **Name of primary investigator(s) and contact person**

2. **Project title:**

3. **Project background *(Please be brief.):***

4. **Question(s) your study will address *(e.g., 'We wish to study the effect of x on y'; Please be concise.):***

5. **Hypotheses your study will test *(e.g., 'We hypothesize that transplant recipients with a higher level of x will have better survival than recipients with lower levels of x.')*:**

6. **Explain why you need to link DMG data to another patient-level source for your study.**

7. **List *key* variables you need for your study so we can confirm the data is available. You may attach a separate list.**

8. **Describe, in general, how the data are to be analyzed *(e.g., organ utilization, survival rates)***

9. **Describe how you plan to use the data, including any plans to present or publish the data.**

10. **Will you need updates of the requested dataset in the future? If yes, describe here.**

DMG REGISTRY DATA LINKAGE AGREEMENT

1. The rights to the released Data are retained by the DMG Registry.

2. Linked data may be made available only after documentation of Institutional Review Board (IRB) review and a waiver of the HIPAA authorization are presented for the proposed study. The DMG Advisory Group must approve the proposed study. If approved and justified, these may be linked to other data sets, consistent with the research plan.

3. The Recipient acknowledges responsibility for submitting a research plan to the Recipient's IRB for review of the research project using the released Data.

4. Upon request, the Recipient will provide the DMG Advisory Group 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 the Recipient will not link or combine the Data with other patient-level information except as set forth in this Agreement and approved by the DMG Advisory Group in writing.

6. The Recipient shall use the Data solely for bona fide research/analysis described in the Research Plan 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 DMG Advisory Group that data would be released to the particular subcontractor, or the Recipient has obtained written authorization from the DMG Advisory Group to release the data to such subcontractor, and (2) the subcontractor has signed a data use agreement with the DMG Registry.

   Before submitting an abstract, manuscript, or other aggregation data to another party for presentation or publication, the Recipient must submit it to the DMG Advisory Group for review to ensure compliance with the terms of this agreement regarding confidentiality. 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 DMG Advisory Group. Upon publication, the Recipient shall provide a copy of the final work and a complete citation to the DMG Advisory Group.

9. 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

10. 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 DMG Advisory Group.

11. All publications using the released Data must contain the standard disclaimer, "The data reported here have been supplied by DMG Advisory Group. 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 DMG Advisory Group."

12. 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.

13. All publications using the released Data must contain this standard statement within the methods section of the publication, "This study used data from the DMG Registry Portal. The DMG data system includes data on deceased donors and transplant recipients, submitted by the members of the DMG Registry."

14. 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.

15. 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.

16. 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.

17. 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.

18. If there are changes in the research plan originally submitted as part of this Agreement, the Recipient must provide to DMG Advisory Group 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 DMG Advisory Group.

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

20. In the event that DMG Advisory Group 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 DMG Advisory Group may notify the Recipient to end the violation and cure the breach. A violation may result in (1) termination of this Agreement immediately and without further notice; and/or (2) disqualification (in whole or in part) of the Recipient at fault and/or any authorized parties from receiving DMG Registry Data in the future.

My signature indicates that I agree to comply with the above stated provisions.

Recipient

Signature: _____ Date: _____

Name:_____

Title:_____

Organization:_____

Appendix 5