



**International Society for Heart & Lung Transplantation
International Thoracic Organ Transplant Registry**

**DATA SHARING AGREEMENT between
INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
and <Name of Collective/OEO>**

This memorandum of agreement (this "Agreement") is made this _____ day of _____, 20____ (the "Effective Date") between The International Society for Heart and Lung Transplantation ("ISHLT") and <Name of Collective/OEO> (the "Data Collective").

Introduction

The International Thoracic Organ Transplant (TTX) Registry is owned and operated by the International Society for Heart and Lung Transplantation (ISHLT). This international Registry collects collect a wide array of demographic, clinical and functional information on thoracic organ transplant recipients of all ages worldwide.

Purpose

The purpose of this Agreement is to define roles and delineate responsibilities of the ISHLT and the Data Collective in the exchange of data relating to thoracic organ transplantation. The purpose of the ISHLT TTX Registry is to collect and analyze clinically relevant data on thoracic organ transplant patients, to enhance the transplant community's understanding of characteristics and outcomes in patients with end-stage organ failure who receive a transplant.

Ownership of Data

Each Data Collective retains ownership of the data submitted to the ISHLT TTX Registry, and grants ISHLT an unrestricted, worldwide, perpetual, fully paid license to such data. The Data Collective may withdraw from the Registry; data previously reported will be retained in the Registry.

ISHLT's Use of Data

ISHLT will only release data in aggregate or de-identified form. ISHLT will respond to requests from a Hospital for reports regarding its own data. Data reporting by the ISHLT which would reveal the individual identity of any Institutions, whose data are submitted to ISHLT via electronic transfer through <Name of Collective/OEO> will not be published or presented without prior approval from that Data Collective. ISHLT will not report center-specific or country-specific data beyond this scope.

ISHLT may distribute the data to additional academic researchers at the Data Collective and at other not-for-profit and/or academic research institutions and/or industry research partners (collectively "Additional Recipients") for the purpose of conducting non-commercial/commercial research activities pertaining and restricted to the furtherance of the ISHLT TTX Registry, and publishing any findings arising there from ("Permitted Uses").

ISHLT may link the data collected through the ISHLT TTX Registry with data from other registries, including but not limited to: ISHLT DCD Registry, ISHLT IMACS Registry, and ISHLT Pediatric Heart Failure Registry (iPHFR), for analytic purposes.

Center Permission for Release of Information:

This agreement will only apply for those <Name of Collective/OEO> transplant centers who agree to the exchange of data between the ISHLT and <Name of Collective/OEO>. <Name of Collective/OEO> will obtain

written permission from its transplant centers to exchange data between ISHLT and <Name of Collective/OEO>. As of the execution of this agreement, these transplant centers are as follows:

- <List of Affiliated Hospitals>

Term of Agreement

The period of performance for this Agreement shall commence on the Effective Date and continue through December 31 of the same year. The Agreement shall automatically be extended for additional one-year periods every December 31, unless the Data Collective or ISHLT gives notice of non-renewal to the other part at least thirty (30) days prior to December 31.

Data Collective Responsibilities

Data Collective agrees to the following:

1. Submit Registry data to the ISHLT TTX Registry via either CSV or Excel files.
2. Submit all transplant data no later than September 30th of each year to be included in the next annual report.
3. Submit the data elements as stated in Appendix A.
4. Institutions, whose data are submitted to ISHLT via electronic transfer through <Name of Collective/OEO>, will be granted electronic read-only access, through the secured ISHLT web interface, to their own institutions center-specific data, as well as ISHLT TTX Registry aggregate data, upon that institution's registration with the ISHLT TTX Registry.
5. Institutions whose data are submitted to ISHLT via electronic transfer will be responsible for making updates to their data through <Name of Collective/OEO>. Updates to their data will not be possible through the online application.
6. Provide the data to the ISHLT for inclusion in the ISHLT TTX Registry in accordance with all applicable laws and in compliance with applicable IRB- or regulatory-approved subject informed consent forms ("ICFs") provided by the individuals from whom the data was collected, or terms of a waiver of consent ("Waiver"), as applicable.
7. Attest that each Hospital's Institutional Review Board (IRB), Privacy Board, or equivalent has approved (or exempted from review) the Hospital's participation in this Registry and that the Hospital meets all local regulatory requirements for participation in the Registry, and will continue to maintain such approval.
8. <Name of Collective/OEO> will provide ISHLT with advance notification of any modifications to scheduled data release(s), format, layout or coding variances.
9. Incomplete data submissions or submissions on partial patient populations are considered non-compliant, and entitle ISHLT, at its discretion, to discontinue the Data Collective's participation in the registry.

ISHLT Responsibilities

ISHLT agrees to the following:

1. ISHLT will provide <Name of Collective/OEO> with data dictionary quality assurance standards (such as general field descriptions) and technical details for each data element collected in the Registry.
2. ISHLT will exclude <Name of Collective/OEO> data submitted to the Registry that:
 1. Does not meet the data submission parameters agreed upon in this Data Sharing Agreement.
 2. Does not conform to the registry data dictionary quality assurance standards provided to <Name of Collective/OEO> prior to the data submission. The agreed upon representative of <Name of Collective/OEO> will be notified regarding reasons for exclusion and will be given the opportunity to resubmit the data once it conforms to the Data Submission Agreement and/or stated quality standards.
3. ISHLT will provide advance notification to <Name of Collective/OEO> of any system and/or

application modifications to the Registry.

4. ISHLT shall use appropriate safeguards to prevent any unauthorized use or disclosure of the data and shall report to the Hospital any unauthorized use or disclosure of which ISHLT becomes aware, or of any breach of this Agreement. ISHLT shall not use the data to identify or contact the individuals from whom the data were collected.
5. ISHLT (or a third party contracted by ISHLT) will host and maintain the Registry in accordance with all applicable laws and the terms of this Agreement. ISHLT will not use/disclose the data other than in accordance with the Permitted Uses as defined above, or as otherwise required by law:
6. Prior to distributing the data in accordance with the Permitted Uses to any Additional Recipient who is not an employee or academic researcher at the Hospital, ISHLT shall require such Additional Recipient to execute a Data Use Agreement with terms consistent with the terms of this Agreement, and to obtain IRB or regulatory approval of the Research Activities for which the Additional Recipient will be using the data. The Data Use Agreement will stipulate that: the Additional Recipient is not permitted to use or further disclose the data, other than as permitted by the Data Use Agreement; the Additional Recipient will report to the ISHLT any use or disclosure of the data of which the Additional Recipient becomes aware, or of any breach of this Agreement; the Additional Recipient shall not use the data to identify or contact the individuals for whom the data were collected.
7. ISHLT will provide periodic reports at least annually to the Hospital that will summarize the data submitted to the Registry by the Hospital.
8. ISHLT will provide advance notification to the Hospital of any important system and/or application modifications to the ISHLT TTX Registry.
9. Periodic Review: Representatives of the ISHLT TTX Registry will confer annually to evaluate operational aspects of this Agreement.

Data Collective/OEO

ISHLT

*Signed: _____

Signed: _____

Name: _____

Name: Amanda W. Rowe

Title: _____

Title: Executive Director, ISHLT

Date: _____

Date: 6/18/2018

*Signature should be made by the appropriate authority to bind the Data Collective to the provisions in the Agreement.

Appendix A: Data Elements
<To be added once agreed upon by Collective/OEO and ISHLT>