



## International Society for Heart and Lung Transplantation Pediatric Heart Failure Registry (iPHFR)

### DATA SHARING AGREEMENT between INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION and \_\_\_\_\_

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  
\_\_\_\_\_. (the "Hospital").

#### **Introduction**

The International Pediatric Heart Failure Registry (iPHFR) is owned and operated by the International Society for Heart and Lung Transplantation (ISHLT). This international Registry intends to enroll and follow pediatric patients with both congenital and acquired heart failure in all countries and hospitals that wish to participate.

#### **Purpose**

The purpose of this Agreement is to define roles and delineate responsibilities of the ISHLT and the Hospital in the exchange of data relating to pediatric heart failure. The purpose of the iPHFR is to collect and analyze clinically relevant data on pediatric heart failure patients in order to better understand the natural history and response to current disease treatment regimens.

#### **Ownership of Data**

Each Hospital retains ownership of the data submitted to the iPHFR, and grants ISHLT an unrestricted, worldwide, perpetual, fully paid license to such data. The Hospital 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 Data reporting by the ISHLT which would reveal the individual identity of any Hospital will not be published or presented without prior approval from that Hospital. ISHLT will not report center-specific or country-specific data beyond this scope.

ISHLT may distribute the data to additional academic researchers at the Hospital 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 iPHFR, and publishing any findings arising there from ("Permitted Uses").

ISHLT may link the data collected through the iPHFR with data from other registries, including ISHLT Transplant Registry, PediMacs, and Pediatric Heart Transplant Study (PHTS).

#### **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 Hospital or ISHLT gives notice of non-renewal to the other part at least thirty (30) days prior to December 31.

## **Hospital Responsibilities**

Hospital agrees to the following:

1. Identify eligible patient participants according to the following criteria.
  - a. Inclusion criteria:
    - Children < 18 years of age
    - With either congenital or acquired heart disease
    - Presenting with symptomatic cardiac failure (NYHA or Ross classification >1) not amenable to surgical correction
    - Asymptomatic patients with sufficient echocardiographic dysfunction for medication to be commenced
  - b. Exclusion criteria:
    - High-flow/shunt lesions as underlying reason for heart failure (e.g. VSD, AVSD, systemic or CNS vascular malformations, catecholamine producing tumors, etc.)
    - Children with correctable lesions (e.g. critical AS, critical PS, etc.)
    - On mechanical circulatory support at time of registration (will be in iMACS registry)
2. Submit Registry data to the iPHFR via [www.ishlt.org](http://www.ishlt.org). Data collection will continue until any of the following terminating events occurs: death, transplant, mechanical circulatory support device implant, or transition of care to a non-participating hospital.
3. Submit all cases no later than September 30<sup>th</sup> to be included in the next annual report.
4. Designate a Program Director as the official contact for IPHFR communications; provide current mail, phone, fax, and e-mail contact information to the IPHFR; and notify the IPHFR immediately if the Program Director has changed.
5. Assume responsibility for maintaining security of its assigned login names and passwords.
6. Provide the data to the ISHLT for inclusion in the iPHFR 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. Provide the iPHFR with documentation verifying that the Hospital's Institutional Review Board (IRB), Privacy Board, or equivalent has approved the Hospital's participation in this Registry and that the Hospital meets all local regulatory requirements for participation in the Registry. If the Hospital is approved for exemption of Board review, written notification of such must be provided to the iPHFR.
8. Incomplete data submissions or submissions on partial patient populations are considered non-compliant, and entitle ISHLT, at its discretion, to discontinue the Hospital's participation in the database.

## **ISHLT Responsibilities**

ISHLT agrees to the following:

1. ISHLT warrants that transmission of data to and from the iPHFR shall be over a secure electronic portal.
2. 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.
3. 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:

4. 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.
5. ISHLT will provide periodic reports at least annually to the Hospital that will summarize the data submitted to the Registry by the Hospital.
6. ISHLT will provide advance notification to the Hospital of any important system and/or application modifications to the IPHFR.
7. Periodic Review: Representatives of the IPHFR will confer annually to evaluate operational aspects of this Agreement.

**Hospital**

**ISHLT**

\*Signed: \_\_\_\_\_

Signed:  \_\_\_\_\_

Name: \_\_\_\_\_

Name: Amanda W. Rowe

Title: \_\_\_\_\_

Title: Executive Director, ISHLT

Date: \_\_\_\_\_

Date: 2/9/2017

\*Signature should be made by the appropriate authority to bind the Hospital to the provisions in the Agreement.