



# **ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)**

## **Memorandum of Agreement Hospital**

**MEMORANDUM OF AGREEMENT**  
**between**  
**INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION**  
**and**  
**[Hospital]**

This memorandum of agreement (this “Agreement”) is made this \_\_\_\_ day of \_\_\_\_\_, 201\_ (the “Effective Date”) between The International Society for Heart and Lung Transplantation (“ISHLT”) and \_\_\_\_\_ (the “Hospital”).

**Introduction**

The International Mechanically Assisted Circulatory Support Registry (IMACS) is owned and operated by the International Society for Heart and Lung Transplantation (ISHLT). This international Registry intends to enroll and follow patients who receive durable mechanically assisted circulatory support devices (MCSD) 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 the implantation and outcome of patients receiving mechanical circulatory support devices (MCSDs). The purpose of the Registry is to understand and advance the application of mechanical circulatory support to improve the lives of patients with advanced heart failure.

**Ownership of Data**

Each Hospital retains ownership of the data submitted to the IMACS Registry. The Hospital may withdraw from the Registry and may request that their data be removed from the Registry.

**Limitations of ISHLT’s use of Exchanged Data**

ISHLT agrees to utilize exchanged data only in aggregate analysis. A Hospital may submit written requests for reports regarding its own data. No center-specific data reporting beyond this scope will be performed. No country-specific data reporting will be performed. Data reporting by the ISHLT which would reveal the individual identity of any Hospital will not be published or presented without prior approval from that Hospital.

**Hospital Responsibilities**

Hospital agrees to the following:

1. Identify eligible patient participants according to guidelines outlined in the accompanying IMACS Protocol, created by the ISHLT.
2. Collect and submit Registry data to the IMACS Registry via [www.ishlt.org](http://www.ishlt.org).
3. Collect and submit complete Registry data at least annually no later than September 30<sup>th</sup> to be included in the next annual report. The following required case report forms should be completed and submitted:

- |                              |                      |                                   |
|------------------------------|----------------------|-----------------------------------|
| *Screening Log               | *Six month follow-up | *Arterial Non-CNS Thromboembolism |
| *Patient Demographics        | *Discharge           | *AE neurological dysfunction      |
| *Pre-implant                 | *Respiratory Failure | *AE device malfunction            |
| *Operative details (implant) | *AE infection        | *Explant/Transplant               |
| *One month follow-up         | *Right Heart Failure | *Death                            |
| *Three month follow-up       | *Bleeding            |                                   |

4. Designate an Administrator as the official contact for IMACS Registry communications, provide current mail, phone, fax, and e-mail contact information to the IMACS Registry, and notify the IMACS Registry immediately if the Administrator is changed.
5. Assume responsibility for maintaining security of its assigned login names and passwords.
6. Provide the IMACS Registry 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 IMACS Registry.
7. Understands that incomplete data submissions or submissions on partial patient populations are considered non-compliant with the ISHLT policies and procedures and entitle ISHLT, at its discretion, to discontinue the Hospital’s participation in the database.

**ISHLT Responsibilities**

1. ISHLT will provide the Hospital 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 provide periodic reports at least annually to the Hospital that will summarize the data submitted to the Registry by the Hospital.
3. ISHLT will provide advance notification to the Hospital of any system and/or application modifications to the IMACS Registry.
4. Periodic Review: Representatives of the Hospital and the IMACS Registry will confer annually to evaluate operational aspects of this Agreement. Unresolved conflict between the Hospital and the IMACS Registry will result in arbitration by an independent third party.

**Agreement**

By signing this Memorandum of Agreement, the Hospital agrees to the terms and conditions outlined in the Agreement and the IMACS Protocol. This Agreement will be renewed automatically annually and may be cancelled with 30 days’ advance written notice by the Hospital or ISHLT.

**Responsible Parties**

We agree to the roles and responsibilities outlined in the preceding Memorandum of Agreement and IMACS Protocol:

**Hospital**

\*Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_ Title: \_\_\_\_\_

**ISHLT**

\*Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_ Title: \_\_\_\_\_

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