



ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)

Memorandum of Agreement Collective

MEMORANDUM OF AGREEMENT
between
INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
And
[Collective]

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 “Collective”).

Introduction

The International Mechanical Circulatory Support Device 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 approved 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 International Society for Heart and Lung Transplantation and the Collective 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

The Collective retains ownership of the data submitted to the IMACS Registry. The Collective 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. No center-specific or country-specific data reporting will be performed on Collective data. No Collective-specific data reporting will be performed unless requested in writing by the official representative of the Collective. Data reporting by the ISHLT which would reveal the individual identity of the Collective will not be published or presented without prior approval of the Collective.

Center Permission of Release of Information

The Collective will obtain written permission from its contributing MCSD centers to exchange data between ISHLT and the Collective. As of the date of signing of this Agreement, these MCSD centers are as follows:

- 1.
- 2.
- 3.

Collective Responsibilities

The Collective agrees to the following:

1. Limit the exchange of data to those patients who have been determined to be eligible according to the guidelines outlined in the IMACS Protocol, created by the ISHLT.
2. Collect and transmit Registry data to the IMACS Data Coordinating Center annually no later than **September 30th** via a mechanism agreed upon by the IMACS Registry and the Collective. Failure

to transmit data by the specified date will prevent the Collective's data from being included in the following annual report.

3. Collect and submit Registry data to include the following required case report forms:

*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. Ensure that each of the Collective's participating Centers have met all institutional and local regulatory requirements regarding the sharing of data with the Collective.
7. Provide ISHLT with advance notification of any modifications to scheduled data release(s), format, layout, or coding variances.
8. Provide ISHLT with a copy of the Collective's Data Verification and Completeness policy.

ISHLT Responsibilities

1. ISHLT will provide the Collective with a data dictionary (such as general field descriptions) and technical details for each data element collected in the Registry.
2. ISHLT will accept no more than one full download annually from the Collective
3. If required data elements are not provided by the Collective and there is no available "code-around", then the data will not be included in the IMACS Registry.
4. The IMACS Registry will receive and verify receipt of data transmissions from the Collective. Data submissions will be reviewed to assess completeness and accuracy. Subsequently, the IMACS Registry will provide the Collective with site-specific verification reports of registrations and follow-up data that meet inclusion criteria for the IMACS Registry.
5. ISHLT will exclude the Collective data submitted to the IMACS Registry that:
 - a. Does not meet the data submission parameters agreed upon in IMACS Protocol.
 - b. Does not conform to the Registry data dictionary quality assurance standards provided to the Collective prior to data submission. The agreed upon Registry Administrator will be notified regarding the reasons for exclusion and will be given the opportunity to resubmit the data once it conforms to the Agreement and/or the stated quality standards.
6. ISHLT will provide advance notification to the Collective of any system and/or application modifications to the IMACS Registry.
7. Reports including aggregate data from all Registry participants and a listing of all Hospitals and Collectives providing Registry data will be made available at least once annually.
8. Institutions whose data are submitted to the IMACS Registry via a Collective will be responsible for making updates to their data through the Collective. Periodic Review: Representatives of the Collective and the IMACS Registry will confer annually to evaluate operational aspects of the Agreement. Unresolved conflict between the Collective and ISHLT will result in arbitration by an independent third party.

Agreement

By signing this Memorandum of Agreement, the Collective 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' written notice by the Collective or ISHLT.

Responsible Parties

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

Collective

*Signature: _____ Date: _____

Printed Name: _____

Title: _____

ISHLT

*Signature: _____ Date: _____

Printed Name: _____

Title: _____

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