Guidelines for the Publication and Presentation of Data from Intermacs

1.0 Preface

This policy document provides guidelines for the publication and presentation of data from the Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs) and refers to all research outputs. This includes traditional publications such as journal articles, books, chapters and conference papers, as well as web-based publications, multi-media, works of art, performances, presentations, software and compositions, etc.

This policy is specific to aggregate, Intermacs data. It does not apply to site-specific data collected locally by each participating hospital. Each site remains the owners of the data they contribute to Intermacs and are free to access, report and publish their own data at any time, provided that, where the Registry is referenced, Intermacs is suitably acknowledged in accordance with this policy. Intermacs does not impose limitations on the use of local hospital data, except that it shall comply with Institutional Review Board, Ethics Review Committee, or Quality Improvement Board conditions and relevant health information privacy legislation.

This policy covers all Intermacs staff, members of the Intermacs committees, device manufacturers, federal agencies and all other stakeholders, including external individuals requesting access to the Intermacs data. Any requests for Intermacs data must be made in accordance with the Intermacs Data Access, Analysis and Publications Policy.

The Intermacs Executive Committee has developed specific **Guidelines for the Publication and Presentation of Data from Intermacs.** These guidelines describe the procedures required to utilize and submit Intermacs data for publication and presentation and to provide guidance to the author(s) on the process for acknowledging such publication or presentation.

- **Use of Intermacs Data for Presentation and Publication**
- **Manuscript Acknowledgements**
- **Standard Paragraph on Patient Confidentiality**
- **Examples of Different Acknowledgments for Using Intermacs Data**
- **Suggested Text for Methods Section**

All publications and research outputs based on aggregate Intermacs data must first be approved by the Intermacs Data Access, Analysis and Publications (DAAP) Committee and/or the Intermacs Executive Committee before submission. Relevant acknowledgements and authorship must be recognized as laid out in this policy.

2.0 Registry Information

2.1 Purpose of the Registry

The **Inte**ragency **R**egistry for **M**echanically **A**ssisted **C**irculatory **S**upport (Intermacs) is a North American registry established in 2005 for patients who are receiving mechanical circulatory support device therapy to treat advanced heart failure. Intermacs was established as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services, clinicians, scientists and industry representatives in conjunction with Dr. James K. Kirklin and the University of Alabama at Birmingham.

2.2 Registry Overview

Intermacs collects clinical data relevant to mechanical circulatory support devices (MCSDs) from index hospitalization through follow-up evaluations. Post implant follow-up data is collected at 1 week, 1 month, 3 months, 6 months and every 6 months thereafter. Major outcomes after implant, e.g., death, explant, rehospitalization and adverse events, are entered within 30 days of occurrence and also as part of the defined follow-up scheduled intervals.

Intermacs provides contemporary data to demonstrate outcomes, with additional insight into appropriate risk stratification and patient selection. Death, transplant, and explant are the major discrete endpoints recorded. Complex endpoints include the patient's level of function and quality of life, critical to the evaluation of current MCSD therapy these indices are becoming increasingly important as patient survival improves, and new devices will be compared for outcomes beyond survival.

Sponsored by The National Heart, Lung and Blood Institute (NHLBI) and housed at the University of Alabama at Birmingham, Intermacs launched in June 2006 with 15 participating hospitals within the United States. The registry has quickly grown to include the majority of MCSD centers in the U.S. Intermacs is recognized as the Joint Commission mandated registry for all U.S. centers implanting MCSDs for destination therapy and now has expanded to include all interested hospitals in the United States and Canada.

2.3 Data Access, Analysis, and Publications (DAAP) Committee

The DAAP Committee addresses issues of access to registry data for proposed research, review of proposed analyses which feature Intermacs data, and review of publications. Recommendations are provided to the Executive Committee about specific analyses which are most useful in addressing the objectives of the registry and the research hypotheses and for prioritization. Interaction between statisticians involved in various aspects of the registry facilitates proper study design, data management and analyses. The Intermacs Data Access, Analysis, and Publications Guidelines are provided at www.intermacs.org.

3.0 Use of Intermacs Data for Presentation and Publication

Access to Intermacs data must be first made in accordance with the Intermacs Data Access, Analysis and Publications Policy. To ensure that the data and any limitations in scope or quality of the data provided has been properly understood by the recipient, abstracts and all pre-publication drafts of any derivative works must be submitted to the DAAP Committee for review. Intermacs must be acknowledged in the appropriate way in all publications and presentations (see below).

Please note that the following apply:

- *Any material or manuscript to be published using Intermacs data must be submitted to the Intermacs DAAP Committee (or delegates) for review prior to submission for publication;*
- *Any material or manuscript to be published using Intermacs data must contain appropriate acknowledgements of Intermacs. Preferred wording for the acknowledgement will be provided with conditions of use specified.*
- *Any PowerPoint slide from Intermacs for presentations is provided on the condition that individual slides are not altered in any way (including background) prior to use. Intermacs will provide a PowerPoint presentation template for the presentation of all Intermacs data at conferences, presentations, etc.*
- *Intermacs requires that researchers provide a copy of any manuscript or presentation in which data, figures, or PowerPoint slides are used. Intermacs maintains a record of all requests for*

Intermacs data and its subsequent use as a means to monitor the value of the registry to the wider clinical community.

4.0 Manuscript Acknowledgements

4.1 Acknowledging the Funding Source

Manuscripts that use Intermacs data must cite the NIH contract number. A typical citation would be: "Data collection for this work was funded in whole or in part with Federal Funds from the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN268201100025C."

4.2 Acknowledging Intermacs Investigators, Coordinators, and Participating Institutions

Intermacs Investigators, Coordinators, and participating institutions appreciate acknowledgment of efforts to collect and make available this valuable data resource. If journals will allow acknowledgments, Intermacs suggests the following option in addition to listing the funding source described above:

"We would like to thank the Intermacs investigators, coordinators, and participating institutions for the data they have provided for this registry."

4.3 Standard Acknowledgment Involving Patient Confidentiality

For all acknowledgments, if the journal requires information about IRB/Ethics approvals and other protections please include the recommended wording:

"The Intermacs Data and Clinical Coordinating Center and each participating institution have received institutional review board/ethics review board approval for either active informed consent or a waiver of consent to enroll participants, link data, and perform analytic studies. All procedures are Health Insurance Portability and Accountability Act (HIPAA) compliant and Intermacs has received a Federal Certificate of Confidentiality and other protection for the identities of patients and devices identified within the Registry.

4.4 Sample Acknowledgments When Utilizing Intermacs Data

- **When one or more authors are Intermacs Co-Investigators (i.e., Publication or Presentation developed by Intermacs):**

"This work was supported in whole or in part with Federal funds from the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services under Contract No. HHSN268201100025C. The content was generated through an INTERMACS collaboration. We would like to thank the Intermacs investigators, coordinators, and participating institutions for the data they have provided for this registry."

- **When Intermacs Co-Investigators are *not* authors (Publication or Presentation is *not* developed by Intermacs):**

"Data collection for this work was supported in whole or in part by the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services under Contract No. HHSN268201100025C. The content is solely the responsibility of the author(s) and does not necessarily represent the official views of the Interagency Registry for Mechanically Assisted Circulatory Support

(Intermacs) or the National Institutes of Health. We would like to thank the Intermacs investigators, coordinators, and participating institutions for the data they have provided for this registry."

- **When including in the Methods Section:**

"Data for this study was obtained from the Intermacs Registry, funded by the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services under Contract No. HHSN268201100025C. More information is available at: www.intermacs.org."