

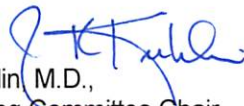


Date: December 1, 2015

Re: **Administrative Change for Protocol Version 1.0, Version date 12/21/12**

To: Sites participating in the ISHLT Mechanically Assisted Circulatory Support Registry

From:


James K. Kirklin, M.D.,
IMACS Steering Committee Chair
Professor & Director, Division of Cardiothoracic Surgery


Sharmene Smith
Program Manager
IMACS Registry

The following administrative change impacts the IMACS Protocol Version 1.0. This letter must be forwarded to your Ethics Board Committee (EC) or regulatory board as soon as possible. The board's acknowledgment must be forwarded to the IMACS Data Coordinating Center.

Please file this letter with all copies of Protocol 1.0. Please file this letter and any EC correspondence in your regulatory file and other pertinent files.

List of Changes to the Protocol Version 1.0:

3.3 Prospective Design

Previous Text: "IMACS is primarily a prospective registry that will collect clinical data, including follow up, essentially as it happens. Post implant follow up data will be collected at 1 week, 1 month, 3 months, 6 months and every 6 months after that. Major outcomes after implant, e.g. death, explant, rehospitalization and adverse events, will be entered as they occur and also as part of the defined follow-up intervals."

Current Text: "IMACS is primarily a prospective registry that will collect clinical data, including follow up, essentially as it happens."

There are a few guidelines that apply to retrospective data entry that all participants must abide by and they are as follows:

- The IMACS Registry Web Based Data Entry system (WBDE) will only accept retrospective data on or after January 1, 2011.
- The site understands that annual reports and most scientific reports produced using IMACS data will only use **prospective data** in its analyses.
- Post implant follow up data will be collected at 1 month, 3 months, 6 months and every 6 months after that. Major outcomes after implant, e.g. death, explant, and adverse events, will be entered as they occur and also as part of the defined follow-up intervals."

The above information will be incorporated into the next version of the protocol if amended.