

The HeartMate II LVAS Post Market Study Protocol

**Sponsor: Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588
(925) 847-8600
(925) 847-8574**

Table of Contents

TABLE OF APPENDICES		IV
1 INTRODUCTION		1
1.1 Background		1
1.2 INTERMACS Registry		1
2 STUDY PURPOSE AND OBJECTIVES		2
2.1 Primary Objectives		2
2.2 Secondary Objectives.....		2
2.3 Outcome Measures		3
3 STUDY Design		3
3.1 Number of Clinical Sites and Patients		3
3.2 Study Duration.....		3
4 Patient Population		3
4.1 Inclusion Criteria.....		4
4.2 Exclusion Criteria.....		4
5 STUDY COURSE		4
5.1 Enrollment Procedures		4
5.2 Patient Assessments:		4
5.2.1 Baseline Assessments.....		4
5.2.1.1 Patient demographic data.....		4
5.2.1.2 Medical history.....		4
5.2.1.3 Clinical status including descriptors of heart failure ...		5
5.2.1.4 Laboratory values		5
5.2.1.5 Medications		5
5.2.1.6 Hemodynamic Data		5
5.2.1.7 Quality of Life (EuroQoL)		5
5.2.1.8 Neurocognitive Testing		5
5.2.1.9 Exercise Function		6
5.2.2 Operative Assessment.....		6
5.2.3 Follow up Assessments		6
5.3 Rehospitalizations		6
5.4 Outcome Information		6
5.5 Adverse Events		7
5.6 Device Malfunctions		7
5.7 Patient Outcome.....		7
5.8 1 Year Post Explant Follow-up:		7

6	DATA ANALYSIS & STATISTICAL ISSUES	8
6.1	Patient Characteristics.....	8
6.2	Outcomes	8
6.3	Additional measures	8
6.4	Rehospitalization	8
6.5	Adverse Events	8
7	ETHICAL AND REGULATORY CONSIDERATIONS	9
7.1	Informed Consent	9
7.2	Institutional Review Board (IRB).....	9
7.3	Monitoring.....	9
7.4	Monitoring Boards	9
	7.4.1 Observational Study Monitoring Board (OSMB)	9
	7.4.2 Adjudication Committee	9
7.5	Patient Confidentiality.....	10
8	DATA COLLECTION	10
8.1	Web Based Data Entry	10

TABLE of APPENDICES

Appendix	Contents
I	INTERMACS Patient Profile/Status
II	Adverse Event Definitions
III	INTERMACS Protocol
IV	INTERMACS User's Guide
V	INTERMACS Electronic Data Form
VI	INTERMACS Informed Consent and HIPAA Authorization

1 INTRODUCTION

1.1 Background

The HeartMate II Bridge to Transplant (BTT) Study was conducted in the United States under Investigation Device Exemption (IDE). A total of 279 patients were enrolled into the HeartMate II Bridge-to-Transplant study at 33 investigational centers in the United States between March 2005 and March 2007. This consisted of 126 enrolled in the initial pivotal trial, 15 small size patients ($BSA < 1.5m^2$) and 138 patients enrolled under the Continued Access Protocol (CAP).

A PreMarket Approval application (PMA) application was submitted to the FDA in December 2006. A reanalysis of the clinical data including the CAP patients was submitted to the FDA on July 23, 2007. The PMA is currently undergoing iterative review. In anticipation of a PMA condition of approval requiring a postmarket study; this document is to define a postmarket study protocol. The purpose of a postmarket study for the HMII LVAS is to assess whether use of the device upon commercial release is comparable to use of the device in the premarket IDE study and to answer any unanswered questions from the PMA review.

1.2 INTERMACS Registry

The Interagency Registry of Mechanical Assisted Circulatory Support (INTERMACS) was formed as a partnership between the National Heart Lung, and Blood Institute (NHLBI), the FDA, Centers for Medicare and Medicaid Services (CMS), participating hospitals and industry, with the intent of generating outcome standards for current clinical device application, providing a platform for introduction of new technology, and acting as a vehicle for the study of patient-device interactions. The data being collected by this registry was determined by experts in the field to be the key measures for determining patient success with use of Ventricular Assist Devices and to allow the analysis of predictors of success and allow comparison among different devices. Though the INTERMACS Registry is voluntary, entering patients into a registry is a requirement for CMS approval as well as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation to implant VADs. The results of data analysis will be used by these agencies to determine the success of individual institution's VAD programs.

As of July 24, 2007, 81 transplant centers have Institutional Review Board (IRB) approval to enter patients into the INTERMACS Registry. These centers represent a thorough cross section of the approximately 150 cardiac transplant centers in the U.S. and include low, medium and high enrolling centers. Thoratec believes that utilizing the data collection capabilities of INTERMACS and the ability to consult with the INTERMACS' experts will be the most expeditious way to collect and analyze postmarket data, as well as the least burdensome approach to complying with a condition of approval post market study. Thoratec will obtain data on a regular basis from INTERMACS to monitor completeness of data collection and to analyze the results of bridge to transplant patients that receive HeartMate II LVADs in a commercial setting.

2 STUDY PURPOSE AND OBJECTIVES

The purpose of this PostMarket Study is to 1) evaluate if data collected in the commercial setting is comparable with data collected in a controlled clinical trial and 2) answer any questions arising from review of the PreMarket Approval Application (PMA).

2.1 Primary Objectives

The primary objectives of the HM II Postmarket Study are:

1. To assess patient outcomes following HMII implantation for Bridge to Transplant – Transplant, Death, and Explant for Recovery.
2. To obtain information about rehospitalizations to address the number of days a patient with the HMII spends in and out of the hospital.

2.2 Secondary Objectives

The following secondary objectives will be evaluated:

1. Incidence of adverse events
2. Clinical reliability (malfunctions/failures)
3. Information about Quality of Life, as measured by EuroQOL instrument
4. Information about reoperations, including device replacements
5. Assessment of general cognitive function as measured by the Trail Making Neurocognitive Test, Part B
6. 1 year post explant survival

2.3 Outcome Measures

The primary objectives for the HM II postmarket study will be as assessment of the rate of survival to transplantation, rate of death and rate of explant for recovery. The rates will be compared to the results in the Premarket IDE clinical trial.

The secondary outcomes will include frequency of adverse events, clinical reliability (rates of device malfunction or failure) improvement in function and quality of life as measured by directional trends, and assessment of general cognitive function.

3 STUDY DESIGN

The postmarket study is a prospective registry of patients receiving the HeartMate II LVAS for Bridge to Transplant indication based on the INTERMACS registry protocol.

3.1 Number of Clinical Sites and Patients

All sites participating in the INTERMACS Registry will participate in the study. At least 81 cardiac transplant centers have IRB approval to enter patients into the INTERMACS Registry as of July 24, 2007. The first fifty (50) patients who give their consent for inclusion in the INTERMACS registry will be included in this postmarket study.

3.2 Study Duration

The patients will be followed in the registry until study outcome; transplant, death or explant for recovery. There will also be an assessment at one year post explant. It is anticipated that this postmarket study will be conducted in 2 ½ years. This includes three months to enroll patients, approximately one year for all outcomes and another year for post transplant follow up.

4 PATIENT POPULATION

All patients receiving a HeartMate II LVAS for the bridge to transplant approved indication per device labeling will be asked to participate in the postmarket registry. Device labeling includes patients refractive to medical therapy who are at imminent risk of death with $BSA \geq 1.3 M^2$.

4.1 Inclusion Criteria

Patient receives a HMII LVAS for Bridge to transplant indication.

1. Patient is refractive to medical therapy and at imminent risk of death
2. $BSA \geq 1.3 M^2$
3. Patient or their legal representative has signed an informed consent for INTERMACS registry participation

4.2 Exclusion Criteria

1. Patients who are incarcerated persons (prisoners)
2. Patients who are participating in an FDA pre-approval study for the HeartMateII LVAS

5 STUDY COURSE

5.1 Enrollment Procedures

Patients scheduled to have HeartMateII LVAS for Bridge to Transplant indication will be asked to sign a consent form for collection of data for the INTERMACS Registry.

5.2 Patient Assessments:

5.2.1 Baseline Assessments

The following baseline data will be collected:

5.2.1.1 Patient demographic data

The standard demographics of age, gender, and patient-described ethnicity will be recorded.

5.2.1.2 Medical history

Heart failure etiology, duration, and standard prognostic factors will be collected along with hemodynamic and echocardiogram parameters closest to the time of implant. Co-morbidities will also be included.

5.2.1.3 Clinical status including descriptors of heart failure

- Seven INTERMACS patient profiles describe the clinical severity at the time of implant. (Appendix II)
- NYHA Class

5.2.1.4 Laboratory values

Assessment of blood chemistries including renal function, liver function, and blood counts

5.2.1.5 Medications

Cardiovascular medications including inotropes, diuretics, antiarrhythmics, pulmonary hypertensive agents, and anticoagulation therapy.

5.2.1.6 Hemodynamic Data

General hemodynamics (heart rate, BP, ECG rhythm), Echo hemodynamics (valve function, left and right ejection fraction, ventricular measurements) and swan hemodynamics (pulmonary artery / wedge pressures, cardiac output)

5.2.1.7 Quality of Life (EuroQoL)

Quality of Life will be measured by administering EuroQoL, a standardized instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as population health surveys.

5.2.1.8 Neurocognitive Testing

Neurocognitive function will be measured by the Trail Making Neurocognitive Test, Part B. This test of general cognitive function also specifically assesses working memory, visual processing, visuospatial skills, selective and divided attention, and psychomotor coordination.

5.2.1.9 Exercise Function

An assessment of exercise function consists of a six minute walk test and pulmonary function measurement of VO₂ max.

5.2.2 Operative Assessment

At the time of surgery information to be collected includes, HeartMate II device tracking numbers, RVAD information (type, tracking numbers), if applicable, concomitant cardiac surgery, cardiopulmonary bypass / surgery time.

5.2.3 Follow up Assessments

Assessments will be made at discharge, 1 week, 1 month, 3 months, 6 months and every 6 months until outcome.

Discharge assessments will include discharge date, hemodynamics, medications, laboratory values, and adverse events.

One week and one month assessments at will include hemodynamics, laboratory values, medications, echocardiogram, medical condition as described by NYHA class and INTERMACS patient status, neurocognitive testing, quality of life testing and adverse events.

Assessments at 3 and 6 months and every 6 months until outcome will also include laboratory values, medications, hemodynamics, echocardiogram, medical condition as described by NYHA class and INTERMACS patient status, neurocognitive testing, quality of life testing, exercise function and adverse events.

5.3 Rehospitalizations

Information regarding rehospitalizations at any time post initial discharge will be collected. Information collected includes date of admission, reason for admission, treatment and date of discharge.

5.4 Outcome Information

Information on the type of outcome (transplant, explant, death) will include transplant date, reason for explant, and cause of death.

5.5 Adverse Events

Information on the following adverse events will be collected; adverse event assessments will include device malfunction, major infection, neurological dysfunction, major bleeding, cardiac arrhythmia, pericardial fluid collection, hemolysis, hepatic dysfunction, hypertension, myocardial infarction, psychiatric episode, renal dysfunction, respiratory failure, right heart failure, arterial non-cns thromboembolism, venous thromboembolism, wound dehiscence, other serious adverse event.

The definitions of all Adverse Event are attached in Appendix II.

5.6 Device Malfunctions

All device malfunctions reported through INTERMACS or reported directly to Thoratec will be reviewed per Thoratec Medical Device Reporting Procedure and reported to the FDA as required by the Medical Device Reporting regulations (21 CFR 803). All malfunctions will be summarized. Thoratec will ensure that malfunctions are also reported by the site to INTERMACS.

Thoratec will conduct analysis on all device components, implants and controllers, returned to Thoratec to confirm malfunction / failure.

5.7 Patient Outcome

Patients will be followed until outcome - transplant, explant, or expiration.

5.8 1 Year Post Explant Follow-up:

If the patient is explanted without transplantation, the patient will be followed for one year following explant for the major events of death or transplant.

6 DATA ANALYSIS & STATISTICAL ISSUES

6.1 Patient Characteristics

Patients who receive HeartMate II will be summarized regarding their demographic data, medical history, and clinical status including descriptors of heart failure, pre-implant laboratory values and pre-implant hemodynamic data. The clinical severity of disease at the time of implantation will be described per INTERMACS profiles.

6.2 Outcomes

Analysis of the outcomes, transplantation, death or recovery will emphasize time related patterns. Death will further be analyzed for each of the causes of death. Analysis will be made of the status of patients at follow-up time points, Kaplan – Meier time to survival to transplant or recovery, and 1 year post explant recovery.

6.3 Additional measures

Analysis will be made of perioperative (30 day) survival, quality of life (EuroQoL) comparison to baseline and Neurocognitive (Trailmaking) comparison to baseline.

6.4 Rehospitalization

Rehospitalization assessment will consist of time in and out of the hospital, percent of patients rehospitalized, and summary of reasons for rehospitalization.

6.5 Adverse Events

An analysis of adverse events will include the examination of the time course for all of the possible patient related and device related adverse events. Analysis will include percent of patients experiencing an event and number of events per patient year.

7 ETHICAL AND REGULATORY CONSIDERATIONS

7.1 Informed Consent

The patient prior to study enrollment must sign an INTERMACS informed consent form. Patients will be asked to sign a Health Insurance Portability and Accountability Act (HIPAA) authorization. The consent must have prior approval from the Institutional Review Board (IRB).

7.2 Institutional Review Board (IRB)

Sites participating in the postmarket study must have IRB approval to collect patient information for inclusion in the INTERMACS Registry.

7.3 Monitoring

The audit process for INTERMACS will include visits to all participating centers. Annual audit visits will begin in year 2 and proceed each consecutive year, through and including year 5. Twenty-five percent of all participating centers will be audited within each calendar year. The schedule has been devised so that all regions and all implant volume categories are represented in audits during each audit year.

7.4 Monitoring Boards

7.4.1 Observational Study Monitoring Board (OSMB)

The role of the OSMB is to monitor both the data collection process and the actual outcomes after implant of a mechanical circulatory support device. The Data Coordinating Center (DCC) of INTERMACS will provide requested information to the OSMB in a timely manner. Along with summaries and analyses that are requested by the OSMB, reports will be submitted semi-annually by INTERMACS to the OSMB.

7.4.2 Adjudication Committee

The INTERMACS Adjudication Committee will meet quarterly. The function of the Adjudication Committee is to review all adverse events and deaths. They will make final decisions regarding causes of death, device failure categories, validation of an adverse event, and any other relevant variables concerning death and adverse events.

7.5 Patient Confidentiality

All patients will sign a consent form to allow their data to be entered into the INTERMACS Registry. Patients will also be requested to sign a HIPAA Authorization. Data summary reports sent to Thoratec will have all data de-identified. Subjects will be coded for tracking purposes. (Example Informed Consent and HIPAA Authorization attached Appendix VI)

8 DATA COLLECTION

The United Network of Organ Sharing (UNOS) will act as the Data Collection Repository for INTERMACS. UNOS will continually evaluate data quality and completeness through consistency checks at data entry, periodic data reports to the sites, and audits. The University of Alabama is the Data Coordinating and Data Analysis Center (DCC) for INTERMACS. The DCC will examine data quality prior to each analysis. The focus will be on completeness of periodic follow-up and also on identifying impossible or improbable combinations of variables. All questionable data points will be referred to UNOS for verification.

Thoratec will receive monthly data reports from the DCC. Thoratec will analyze the data completeness and questionable data points. Thoratec will work with the individual sites, and the DCC to clarify questionable data points.

8.1 Web Based Data Entry

All data will be entered through the INTERMACS web based data entry system. (Attached Data Entry Screens Appendix V, User's Guide Appendix IV)

Appendix I

INTERMACS Patient Profile/Status

INTERMACS Patient Profile/Status

- 1 “Critical Cardiogenic Shock”: low BP unresponsive to support, compromised organ perfusion, < 24 hours survival expected without mechanical support
- 1A “Critical Cardiogenic Shock”: low BP unresponsive to support, compromised organ perfusion, < 24 hours survival expected without mechanical support Modifier A “Recurrent VT/VF”
- 2 “Progressive Decline”: not in imminent danger but worsening despite inotropic support, with declining renal function, nutrition, ambulation, other
- 2A “Progressive Decline”: not in imminent danger but worsening despite inotropic support, with declining renal function, nutrition, ambulation, other Modifier A “Recurrent VT/VF”
- 3 “Stable but Inotrope dependent”: unable to be weaned from inotropic support
- 3A “Stable but Inotrope dependent”: unable to be weaned from inotropic support Modifier A “Recurrent VT/VF”
- 4 “Recurrent advanced heart failure”: recurrent congestion despite good maintenance, needing repeated interventions beyond escalation of oral diuretics
- 4A “Recurrent advanced heart failure”: recurrent congestion despite good maintenance, needing repeated interventions beyond escalation of oral diuretics Modifier A “Recurrent VT/VF”
- 5 “Exertion intolerant”: comfortable at rest without obvious fluid overload but limited activities of daily living (ADL)

- 5A “Exertion intolerant”: comfortable at rest without obvious fluid overload but limited activities of daily living (ADL) Modifier A “Recurrent VT/VF”

- 6 “Exertion limited”: comfortable at rest and with ADL but meaningful activity limited

- 6A “Exertion limited”: comfortable at rest and with ADL but meaningful activity limited Modifier A “Recurrent VT/VF”

- 7 “Advanced NYHA Class 3”

This page intentionally left blank.

Appendix II

Adverse Event Definitions



Interagency Registry of Mechanically Assisted Circulatory Support

Adverse Event Definitions



Major Bleeding

An episode of internal or external bleeding that results in death, the need for re-operation or hospitalization; or necessitates transfusion of red blood cells as follows:

Within any 24 hour period:

- 1) ≥ 4 U packed red blood cells (PRBC) within any 24 hour period during the first 7 days post-implant
- 2) Any transfusion of packed red blood cells (PRBC) after 7 days following implant with the

Investigator recording the number of units given.

For patients < 50 kg:

- 1) ≥ 20 cc/kg packed red blood cells (PRBC) within any 24 hour period during the first 7 days post-implant
- 2) Any transfusion of packed red blood cells (PRBC) after 7 days following implant with the

Investigator recording the number of units given.

NOTE: Hemorrhagic stroke is considered a neurological event and not as a separate bleeding event.

Cardiac Arrhythmias

Any documented arrhythmia that results in clinical compromise (e.g., diminished VAD flow, oliguria, pre-syncope or syncope) that requires hospitalization or occurs during a hospital stay. Cardiac arrhythmias are classified as 1 of 2 types:

- 1) Sustained ventricular arrhythmia requiring defibrillation or cardioversion.
- 2) Sustained supraventricular arrhythmia requiring drug treatment or cardioversion.

Pericardial Fluid Collection

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (e.g. increased central venous pressure and decreased cardiac/VAD output) and those without signs of tamponade.

Device Malfunction

Device malfunction denotes a failure of one or more of the components of the MCS system which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. The manufacturer must confirm device failure. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.

Device failure should be classified according to which components fails as follows:

- 1) **Pump** failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of **pump thrombosis**, thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure.
- 2) **Non-pump** failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)

Hemolysis

A plasma-free hemoglobin value that is greater than 40 mg/dl, in association with clinical signs associated with hemolysis (e.g., anemia, low hematocrit, hyperbilirubinemia) occurring after the first 72 hours post-implant. Hemolysis related to documented non-device-related causes (e.g. transfusion or drug) is excluded from this definition.

Hepatic Dysfunction

An increase in any two of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase/**AST** and alanine aminotransferase/**ALT**) to a level greater than three times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death) .

Hypertension

New onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).

Pediatric patients: for patients under 18 years of age weighing < 50 kg, hypertension is defined as systolic, diastolic, or mean blood pressure greater than the 95th percentile for age which requires the addition of iv or oral therapy for management.

Major Infection

A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

Localized Non-Device Infection

Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (see sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Pocket Infection

A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy, when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection

Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

Sepsis

Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.

Myocardial Infarction

Two categories of myocardial infarction will be identified:

Peri-Operative Myocardial Infarction

The clinical suspicion of myocardial infarction together with CK-MB or Troponin > 10 times the local hospital upper limits of normal, found within 7 days following VAD implant together with ECG findings consistent with acute myocardial infarction. (This definition uses the higher suggested limit for serum markers due to apical coring at the time of VAD placement, and does not use wall motion changes because the apical sewing ring inherently creates new wall motion abnormalities.)

Non-Perioperative Myocardial Infarction

The presence at > 7 days post-implant of two of the following three criteria:

- a) chest pain which is characteristic of myocardial ischemia,
- b) ECG with a pattern or changes consistent with a myocardial infarction, and
- c) Troponin or CK (measured by standard clinical pathology/laboratory medicine methods) greater than the normal range for the local hospital with positive MB fraction ($\geq 3\%$ total CK). This should be accompanied by a new regional LV or RV wall motion abnormality on a myocardial imaging study.

Neurological Dysfunction

Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard neurological examination (administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note). The examining physician will distinguish between a transient ischemic attack (TIA), which is fully reversible within 24 hours (and without evidence of infarction), and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). The NIH Stroke Scale (for patients > 5 years old) must be re-administered at 30 and 60 days following the event to document the presence and severity of neurological deficits. Each neurological event must be subcategorized as:

- 1) Transient Ischemic Attack (acute event that resolves completely within 24 hours with no evidence of infarction)
- 2) Ischemic or Hemorrhagic Cardiovascular Accident/CVA (event that persists beyond 24 hours or less than 24 hours associated with infarction on an imaging study).

In addition, to above, for patients < 6 months of age, any of the following:

- 3) New abnormality of head ultrasound
- 4) EEG positive for seizure activity with or without clinical seizure

Psychiatric Episode

Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress requiring intervention. Intervention is the addition of new psychiatric medication, hospitalization, or referral to a mental health professional for treatment. Suicide is included in this definition.

Renal Dysfunction

Two categories of renal dysfunction will be identified:

Acute Renal Dysfunction

Abnormal kidney function requiring dialysis (including hemofiltration) in patients who did not require this procedure prior to implant, or a rise in serum creatinine of greater than 3 times baseline or greater than 5 mg/dL (**in children**, creatinine greater than 3 times upper limit of normal for age) sustained for over 48 hours.

Chronic Renal Dysfunction

An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for hemodialysis sustained for at least 90 days.

Respiratory Failure

Impairment of respiratory function requiring reintubation, tracheostomy or (for patients older than age 5 years) the inability to discontinue ventilatory support within six days (144 hours) post-VAD implant. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures.

Right Heart Failure

Symptoms and signs of persistent right ventricular dysfunction [central venous pressure (CVP) > 18 mmHg with a cardiac index <2.0 L/min/m² in the absence of elevated left atrial/pulmonary capillary wedge pressure (greater than 18 mmhg), tamponade, ventricular arrhythmias or pneumothorax] requiring RVAD; implantation; or requiring inhaled nitric oxide or inotropic therapy for a duration of more than 1 week at any time after LVAD implantation.”

Arterial Non-CNS Thromboembolism

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

- 1) standard clinical and laboratory testing
- 2) operative findings
- 3) autopsy findings

This definition excludes neurological events.

Venous Thromboembolism Event

Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing.

Wound Dehiscence

Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

Other

An event that causes clinically relevant changes in the patient's health (e.g. cancer).

Appendix III

INTERMACS Protocol



A. INTERMACS PROTOCOL

- 1.0 Executive Summary
- 2.0 Study Description and Purpose
- 3.0 Registry Design
 - 3.1 Patient Eligibility
 - 3.2 Prospective Design
 - 3.3 Additional Datasets
 - 3.4 Major End Points
 - 3.5 Observational Study Monitoring Board (OSMB)
- 4.0 Patient Safety
 - 4.1 Risks and Benefits
 - 4.2 IRB Review and Approval
 - 4.3 Informed Consent Process
- 5.0 Data Collection
 - 5.1 Web based data entry
 - 5.2 Clinical Data
 - 5.3 Quality of Life Data
 - 5.4 Neuro-cognitive Data
 - 5.5 Blood and Tissue Samples
- 6.0 Analyses of Registry Data
- 7.0 Periodic Statistical Summaries
 - 7.1 NHLBI
 - 7.2 FDA
 - 7.3 CMS
 - 7.4 Industry
 - 7.5 Individual hospitals
 - 7.6 OSMB
- 8.0 Quality assurance

A. PROTOCOL

1.0 Executive Summary

INTERMACS (Registry for Mechanically Assisted Circulatory Support)

Contract [REDACTED]

Data Coordinating Center [REDACTED]

Principal Investigator: [REDACTED]

The goal of INTERMACS is to establish a registry of patients receiving a mechanical circulatory support device (MCSD) to treat heart failure. These activities will be supported by a data and clinical coordinating center (DCC) under contract to the National Heart, Lung, and Blood Institute (NHLBI). The purpose of the registry is to collect and analyze clinical and laboratory data and tissue samples from patients who are receiving MCSDs for whom discharge from the hospital is feasible. This would include MCSDs intended as destination therapy for end stage heart failure and patients receiving a MCSD for bridge to transplantation provided hospital discharge is feasible. It is anticipated that the registry will collect data, blood and tissue samples from approximately 70 participating hospitals and 1,000 new patients per year for a period of 5 years.

Broadly, the registry will enable research to determine best medical practices for advancement of public health with respect to the use of MCSDs for the treatment of heart failure. The registry will: 1) develop standard methods to collect data and specimens which will be used for research to characterize heart failure patients receiving MCSDs, demographics of MCSD use, and patient outcomes; 2) collect, process, and store patients' clinical data and tissue/blood samples; 3) analyze data collected; 4) provide these resources to researchers outside the registry who are interested in advancing the application of MCSDs for patients with heart failure; and 5) publish and disseminate results. Aggregated data reports from the registry will be shared with the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) through an Interagency Agreement. FDA is interested in patient/device outcomes as a way to monitor safety, and CMS is interested in improving economic outcomes by identifying and optimizing factors affecting cost-effectiveness. Following a plan for dissemination, data and biological specimens will be shared with basic and clinical researchers, with consideration for privacy regulations. Analytic strategies and data analysis will be conducted by the DCC resulting in publications, presentations, and follow-up investigations.

The MCSD registry through its Data Coordinating Center (DCC) will collect information pertaining to patients, care providers, hospitals, and devices. Much of these data will be collected through chart review by nurse coordinators and physicians at the clinical sites. Efforts are underway to develop agreements to allow the import of relevant data from the Health Resources and Service Administration's (HRSA) Organ Procurement and Transplant Network (OPTN) heart transplant database. Quality of life (QoL) data will be collected through the administration of the EuroQOL sixteen-item instrument by adult registrants pre-implant and at 3 months, 6 months, and every 6 months post implant. Neurocognitive data from the Trail Making Test will be collected similarly to the quality of life data. The registry will also collect and store blood and tissue specimens in the NHLBI supported tissue repository.

The intention is to collect data on all patients receiving MCSDs on an ongoing basis at all participating sites. Standardized data collection forms and practices will be followed utilizing a web-based system. All Privacy Act provisions will be followed in handling and storing patient information and samples.

The DCC has developed in consultation with the Steering Committee, an informed consent document and model protocol to be used by each participating hospital in its preparation of materials for their IRB review and approval. All participating centers will obtain IRB approval before collecting registry data.

Patients will be consented prior to case data being included in the registry. An NHLBI-appointed independent Observational Study Monitoring Board (OSMB) will be established to evaluate the registry on an ongoing basis as to procedures, findings, and adverse events to assure participant safety, confidentiality of records, and registry integrity. The OSMB will advise the NHLBI when and if changes should be made. It is anticipated the OSMB will meet at least yearly.

Collaborators receiving funding on this project include:

2.0 Study Description and Purpose

The fundamental goal of INTERMACS (the **I**nteragency **R**egistry of **M**echanically **A**ssisted **C**irculatory **S**upport) is to advance the understanding and application of mechanical circulatory support in order to improve the duration and quality of life in patients with advanced heart failure. These activities will be supported by a data and clinical coordinating center (DCC) at the University of Alabama at Birmingham under contract to the National Heart, Lung, and Blood Institute (NHLBI). INTERMACS will function as a partnership between NHLBI, the FDA, CMS, participating hospitals, and industry; with the intent of generating **outcome standards for current clinical device application**, providing a platform for **introduction of new technology**, and acting as a vehicle for the study of **patient-device interactions**.

Goals of the Registry

- Facilitate the refinement of **patient selection** to *maximize outcomes* with current and new device options.
- Improve and expedite **new device clinical trials** by providing historical control data, reliable enough to serve as *Objective Performance Criteria (OPC)* standards for FDA.
- Develop consensus “*best practice*” guidelines to improve **clinical management** by reducing short and long term complications of MCS therapy.
- Improve **economic outcomes** by identifying and optimizing factors affecting *cost-effectiveness*.
- Utilize MCS Registry information to guide improvements in **technology**, particularly as *next generation devices* evolve.
- Promote **research** into the underlying pathophysiologic substrate of advanced heart failure in order to define and promote the conditions necessary for *myocardial recovery*.
- Evaluate parameters of **functional capacity** and **quality of life** before and after device implantation.
- **Disseminate registry research results** through peer-reviewed journals and other publications.

Specific Strategies to Achieve Registry Goals

- A. Organize hospitals implanting durable (having the potential for hospital discharge) mechanical support devices to partner in these objectives by providing critical data on MCSD therapy
 - Develop criteria for hospitals to become participating members, implement performance quality standards, and develop procedures for eliminating hospitals with poor data collection compliance
- B. Implement streamlined data collection which will describe the patient heart failure condition and device characteristics; and target major endpoints in MCSD therapy
 - Develop protocols for the collection of clinical data on MCSD patients and implement the collection and storage of data for the purposes of characterization of heart failure patients who undergo MCSD therapy, examination of adverse events after MCSD implantation, and assessment of patient and device outcomes
 - Develop a manual of operations, study forms, and informed consent documents
 - Develop protocols, methods, and procedures for the collection of blood and tissue samples
- C. Perform data analyses aimed at Improving MCSD therapy and clarifying the evolving role of this life-saving therapy for advanced heart failure
 - Provide detailed statistical analyses of collected data aimed at improving patient outcomes through neutralization of patient-specific risk factors
 - Analyze endpoints and their determinants to better utilize this unique therapy
 - Develop baseline risk profiles that will eventually allow comparison of expected outcomes for individual patients with and without devices and/or transplantation.
- D. Enhance MCSD therapeutic outcomes at participating hospitals through their participation in the Registry.
 - Provide center-specific reports (containing confidential analyzed data for that individual center as well as aggregate registry data) at 6 month intervals for purposes of center improvements in MCSD outcomes, CQI, and institutional review processes.
 - Share aggregate risk-adjusted data among institutions to improve patient selection and reduce adverse events.
- E. Promote participation of outside researchers to advance knowledge in device therapy and the potential reversibility of advanced heart failure
 - Facilitate interactions among participating hospitals and researchers and provide administrative logistic support for publications
 - Facilitate access to blood and tissue samples for research into myocardial recovery
- F. Share data with governmental agencies, industry, research investigators, and clinical communities
 - Provide customized reports to NHLBI, CMS, FDA, and OSMB
 - Provide customized reports to industry based on each company's implanted devices.
 - Publish and disseminate results of scientific registry studies
 - Convene consensus conferences to establish "best practice" guidelines
- G. Partner with industry to improve and expedite new device trials

3.0 Registry Design

3.1 Patient Eligibility

Scope

The scope of INTERMACS encompasses those patients receiving mechanical circulatory support devices (MCS) for whom discharge from the hospital is feasible. These devices are defined to be “durable” devices. There is no exclusion for age, gender, race, or ethnicity.

Inclusion Criteria

All patients with a MCS implanted on or after 3-1-2006 will be included whether it is their 1st, 2nd, or 3rd device. The Registry will include every consented patient who receives an eligible MCS (as listed below) at a participating center, regardless of reason: bridge-to-recovery, bridge-to-alternative bridge, bridge-to-clinical improvement for transplant eligibility, bridge-to-transplant, or destination therapy.

Included patients:

1) Patients who receive a durable mechanical circulatory support device (MCS) which is FDA approved.

2) Patients who receive an MCS after the hospital is activated (i.e., has received local IRB approval and has gained access to the INTERMACS database). Patients who received an MCS after March 1st, 2006 and before the hospital activation date, IF the local IRB allows this inclusion criterion.

3) Patients who have signed informed consent for the registry.

Exclusion patients:

There is no exclusion for age, gender, race, ethnicity, or any other demographic limit.

Excluded patients:

1) Patients who are Incarcerated persons (prisoners).

2) Patients who fulfill the eligibility criteria but are part of an FDA pre-approval study (these patients will be entered into the clinical trial database that is maintained by the device manufacturer).

Although no distinction is made between adult and pediatric patients in INTERMACS, additional data is requested for pediatric patients (<19 years of age) and for adult patients with congenital diagnoses. These data elements have been framed in red boxes. For adult (non-congenital) patients, you will not see these data elements.

Once a patient is entered as a pediatric patient, the patient will remain in pediatric status until the implanted device is explanted.

Please refer to the INTERMACS Protocol 3.1 'Patient Eligibility' and Appendix K. 'Device Brand List' for further information. These documents are available online at www.intermacs.org and selecting "All Things INTERMACS" – "Manuals".

Follow-up and Censoring

All patients will be followed as long as a MCSD is in place. If a patient has a MCSD removed and is not transplanted, then the patient will be followed for 1 year Vital status including transplantation and survival will be determined during this year.

Link to OPTN Database for Transplantation

If a patient has an MCSD removed and is immediately transplanted, then the patient is no longer followed in INTERMACS. At that time, the patient becomes part of the Organ Procurement and Transplant Network (OPTN) transplant database and will be followed by that database. A patient undergoing transplantation more than one year after explantation will be included in INTERMACS for the first year, and then will re-enter follow-up through the OPTN at the time of transplantation.

If a patient transfers his/her care to: (a) a non-INTERMACS institution, then the patient is censored at the time of transfer, but all attempts should be made to determine vital status at yearly intervals; (b) an INTERMACS institution, then the patient will continue to be followed at the new institution (using the original patient ID number).

3.2 Prospective Design

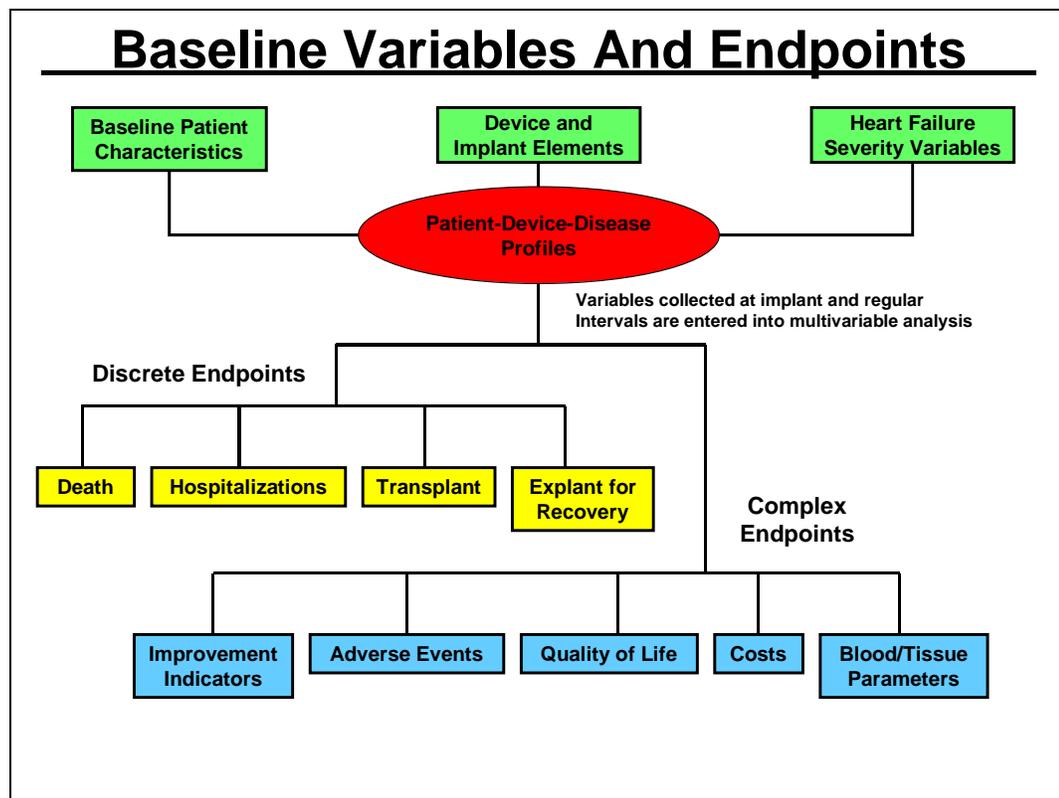
INTERMACS is a prospective registry that will enter clinical data, including follow up, essentially as it happens. Post implant follow up data will be collected at 1 week, 1 month, 3 months, 6 months and every 6 months after that. Event driven data will be collected for death, explant, rehospitalization, and three adverse events: neurological dysfunction, infection, and device malfunction.

3.3 Additional Datasets

Once the web based data entry of INTERMACS is fully operational, each site will have the option of retrospective entry of patients receiving MCSD therapy prior to a site's start date for prospective patient entry. There are three possibilities:

- A. The MCSD registry of the International Society of Heart and Lung Transplantation (ISHLT) closed down the United States portion in ~~January~~ July 2006. A site may move these patients into INTERMACS and prospective follow up on the surviving patients will begin. The details of this process (including IRB approval and informed consent) will be worked out after the launch of INTERMACS.
- B. A site may enter other retrospective patients that were not collected by the ISHLT MCSD registry back to March 1, 2006. The IRB and informed consent process will be similar to the prospective INTERMACS patients.
- C. With cooperation between industry and INTERMACS, patients who were part of FDA device approval studies may be moved into INTERMACS. The Process for acquiring this data will be developed on a case-by-case basis.

3.4 Major End Points



At the current stage of mechanical circulatory support technology, reported one year survival is in the range of 40-60% for the randomized trial experience of REMATCH destination therapy and for the initial analysis of the 413 patients in the current ISHLT MCSDB database. INTERMACS will provide contemporary data to demonstrate the continued progress of outcomes, with additional insight into appropriate risk stratification and patient selection. Death, transplant, and explant will be the major discrete endpoints recorded, to provide the most fundamental outcome statistics.

Information about rehospitalizations will be vital to address the integrated endpoint of days alive out of hospital, which is particularly relevant for the patient population with advanced heart failure or with ventricular assist devices, as re-hospitalizations are common but not of the same hierarchical importance as death. In addition, the number of hospital days will be closely tracked as the major resource utilized, after the initial implant. Any subsequent surgery or implants will also be noted as additional resources in addition to the hospital days required. Specific attention will be devoted to capturing the number of days in hospital in order to provide a relative estimate of cost.

The **complex endpoints** that include the patient's level of **function and quality** of life are also critical to the evaluation of current MCSDB therapy, for which improvements in both survival and function have been compelling. These indices will become increasingly important as the survival improves, and new devices will be compared for outcomes beyond survival. When comparing device therapy to medical therapy, estimates of quality-adjusted survival and cost-effectiveness require quantification of quality and estimates of cost based on resource utilization, as discussed above.

Definition and recording of adverse events will be important aspects of this database. With firm denominators, the incidence and prevalence of adverse events will be made within the context of device type, management practices, patient co-morbidities, timing of implantation, surgical experience and technique; all based on the consistency of uniform adverse event definition. Each adverse event will be separately categorized as primary (the major or initiating in a series of adverse events) or secondary (a sequelae of a primary event). For each adverse event, additional variables must be included which potentially allow a determination of whether an adverse event most likely resulted from device design failure or malfunction (**device-related**), patient co-morbid conditions (**patient-related**), or errors in patient management (e.g. inadequate anti-coagulation) (**management-related**).

3.5 Observational Study Monitoring Board (OSMB)

An NHLBI-appointed independent Observational Study Monitoring Board (OSMB) will be established to evaluate the registry on an ongoing basis as to procedures, findings, and adverse events to assure participant safety, confidentiality of records, and registry integrity. The OSMB will advise the NHLBI when and if changes should be made. It is anticipated the OSMB will meet at least yearly.

The principal role of the Observational Study Monitoring Board (OSMB) is to monitor regularly the data from the registry, review and assess the performance of its operations, and make recommendations, as appropriate, to the Institute with respect to:

- the performance of individual centers (including possible recommendation on actions to be taken regarding any centers that performs unsatisfactorily);
- issues related to participant safety and informed consent (if required), including notification of and referral for abnormal findings;
- adequacy of study progress in terms of recruitment, quality control, data analysis, and publications;
- issues pertaining to participant burden;
- impact of proposed ancillary studies and sub studies on participant burden and overall achievement on the main study goals;
- possible modifications in the study protocol; and
- overall scientific direction of the registry

The OSMB is composed of a Chair and members with expertise in biostatistics, clinical trials, bioethics, heart failure, cardiac surgery, bioengineering and device complications. Consultants may be added to the OSMB when it may be helpful to have greater representation of expertise in the relevant scientific field. All standing members of an OSMB may vote. Consultants have the same voting rights as an official OSMB member when reviewing the protocol.

Individuals are invited to serve on the OSMB by the NIH Director. Members are required to complete a Conflict of Interest Certification for review and acceptance by the institute prior to serving on the Board. At the beginning of all meetings the Chair or the Executive Secretary (ES) will verbally remind the members of the importance of avoiding conflicts of interest and that members must notify the ES promptly if any changes occur which may pose a potential conflict of interest.

The ES is an NIH staff member, other than the Project Officer, appointed by the Division Director. The ES is responsible for working with the OSMB Chair to ensure the Board fully considers the data pertaining to the participants' safety and study integrity; engages in full

discussion of relevant issues; and addresses issues of protocol modifications and contraindications to participant enrollment.

OSMB members will meet face-to-face on a regular basis. Interim meetings may be held and, when appropriate, may be conducted by conference call. Meeting attendees typically include OSMB members; the ES; NIH staff, including a biostatistician; Coordinating Center representatives; Steering Committee Chair; and ad hoc consultants or other representatives invited to the meeting on an as needed basis.

The ES will prepare the agenda for meetings after consultation with the OSMB Chair, NIH staff, and Coordinating Center staff. The agenda may include an Executive Session. Executive Sessions may exclude non-voting members, with the exception of the ES. NIH representatives will attend an Executive Session on an as needed basis.

The ES will prepare minutes for all meetings. The minutes will include general recommendations, action items, any protocol changes or study Coordinating Center recommendations, the justifications for these recommendations, and the estimated time frame for the next meeting. Minutes will not typically include confidential trials outcome data.

OSMB Responsibility	Possible Materials
Completeness, quality, and analysis of measurements that are made	Plans/procedures for data collection and monitoring data quality
Adequacy of data submission from individual centers (including possible recommendations on actions to be taken regarding any center that performs unsatisfactorily)	Plans/procedures to monitor performance – e.g. participant accrual, data accuracy and timeliness, protocol compliance, compliance with federal regulations, long-term patient follow-up, and on-site data audits
Interim results of study for evidence of safety or adverse events	Plans/procedures for monitoring adverse events and outcomes of interest Draft Table of Contents for OSMB Report Book to facilitate discussion on format and content.
Possible protocol modifications	Procedures for amending protocols

Draft minutes will be sent to the Chair for review and then signed by the Chair and the ES. The signed minutes will be distributed to OSMB members prior to the next meeting. The ES will communicate relevant recommendations and may send excerpts of the minutes to the Steering Committees and Coordinating Center. Following each meeting, the NIH Project Officer will prepare a Summary Report, for distribution to each participating center's Principal Investigator, as described in the registry procedures for reporting adverse events to local Institutional Review Boards.

First OSMB Meeting

The agenda for the first meeting of the OSMB will include an overview of the role and the responsibilities of the OSMB; a discussion on the format, including a distribution timeline for the presentation of ongoing data; and the process the Board will use to make recommendations on continuing a study.

In addition, the OSMB will discuss the registry monitoring plans for data quality and subject safety. The table above presents possible materials that may be used to address the OSMB responsibilities in this area. Of note, the Data Coordinating Center, in consultation with the Steering Committee, will be responsible for determining the selection and organization of the materials. Questions regarding meeting materials may be sent to the ES.

Meeting materials will be distributed by the Coordinating Center. The Coordinating Center will consult with the ES regarding distribution timelines. It is the responsibility of the ES to ensure OSMB members receive data reports with sufficient time for review.

Review of Study Protocol

Once the protocol is finalized, the OSMB will review the study protocol and monitoring plans. The OSMB review will focus on data quality and safety assurance. The OSMB must accept the protocol before participant enrollment begins.

For the initial protocol review, the following materials should be provided to OSMB members:

- final protocol
- manual of operations
- informed consent document (prototype)
- data and safety monitoring plan
- study policies regarding COI, publications, and data sharing
- detailed recruitment goals

Additional materials to address data quality and participant safety on the study should also be supplied. The Data Coordinating Center, in consultation with the Steering Committee, will be responsible for determining the selection and organization of the materials. Questions regarding meeting materials may be sent to the ES.

Meeting materials will be distributed by the Coordinating Center. The Coordinating Center will consult with the ES regarding distribution timelines. It is the responsibility of the ES to ensure OSMB members receive data reports with sufficient time for review.

At the end of each review the ES will ask the OSMB members to vote regarding acceptance of the study protocol. The OSMB recommendation will be directed to the Institute for implementation as appropriate.

Data Oversight

The registry Coordinating Center will prepare and distribute data reports. The basic format for the presentation of ongoing data and the need to provide these data within a certain time frame will be established at the initial OSMB meeting. Prior to each meeting, the ES and other program staff should review the data and materials and, if needed, communicate with the Coordinating Center. It is the responsibility of the ES to ensure OSMB members receive data reports with sufficient time for review.

When important issues, such as complications of therapy, breaches of the protocol, or other major issues impacting on the conduct of the study are discussed during a meeting, the ES will document the discussions and the outcome. The ES will work with the OSMB to discern and assess critical issues such as:

- failure to comply satisfactory with recruitment goals, including those related to the participation of women and minorities;
- trends of increased or decreased morbidity and/or mortality observed
- adverse events;
- the unsatisfactory performance of the Coordinating Center and/or study centers;
- suspicion of fraud; and
- any other issues that would lead to important protocol changes.

If such issues arise, the ES will discuss the situation with the appropriate NIH staff, including grants management or contracts operations staff, and notify the NIH Director promptly. Some ways in which the NIH may respond to such issues include: expanding the number of enrolling centers, extending the period of recruitment, stopping recruitment because of inadequate rate of acquisition, modifying the protocol (in collaboration with the Investigators/ Steering committee), or discontinuing a center with poor performance. It may also elect to establish an ad hoc committee to provide assistance in these matters. Such ad hoc committees may include representation from initial reviewers, OSMB members, and members of the relevant scientific community.

4.0 Patient Safety

4.1 Risks and Benefits

Risks

The data collected for this Registry are from medical chart abstraction and remnant surgical material. The only exception is the collection of Quality of Life data via patient interviews and neurocognitive data collected via the Trail Making Test. The interviews and tests are not considered greater than minimal risk but may trigger uncomfortable feelings about one's quality of life.

Benefits

There is no guarantee of direct benefit to the heart failure patients who participate in this registry. There is the possibility that some patients will experience longer life if analysis and dissemination of results improve the performance of their particular mechanical circulatory assistance device. Some patients may benefit from the knowledge that they are helping to advance knowledge for future heart failure patients.

4.2 IRB Review and Approval

In preparation of materials for IRB review and approval, participating sites will use the informed consent document and model protocol developed by the DCC in cooperation with the Steering Committee. All participating centers will obtain IRB approval before collecting registry data. Dated proof of IRB and Informed Consent approval will be sent to the DCC. The DCC will send annual reminders at least 30 days prior to expiration of IRB. Lapse in local IRB coverage will result in immediate suspension of data entry capability.

4.3 Informed Consent Process

Patients will be consented prior to case data being included in the registry. Signed informed consent documents will be kept in a double-locked area at the participating site. Informed consent documents with patient signatures will not be sent to the DCC.

5.0 Data Collection

5.1 Web based data entry

All data will be entered through the INTERMACS web based data entry system. Complete documentation and the User's Guide are contained at the data entry website (www.intermacs.org).

This system is prospective, i.e. the forms should be filled out as the implant and follow-up events occur (within specific time windows). We have attempted to make the data entry strategy as straight forward and intuitive as possible. The data are divided into forms that correspond to the clinical time course of the patient.

5.2 Clinical data

Clinical data will be collected by medical chart review.

Patient Demographics and Profile Prior to Implant: The standard demographics of age, gender, and patient-described ethnicity will be recorded. Heart failure etiology, duration, and standard prognostic factors will be collected along with hemodynamic and echocardiographic parameters closest to the time of implant. Co-morbidities will be included, as they may affect the likelihood of success of MCS therapy compared to other options. A novel aspect of the data elements is the establishment of 7 INTERMACS profiles that will describe the clinical severity at the time of implant, aid in risk stratification, improve patient selection, and refine the definition of future trial populations. INTERMACS also seeks to transition away from the artificial distinction of bridge versus destination intent, by recording, before and at intervals after implant, the relative likelihood and limiting factors for transplant eligibility.

Device and Operative Details (implant): The critical elements which characterize the device and describe the implant procedure will be recorded at the time of implant.

Designated Interval Follow-up: A major feature of the data base design is the provision of information both by event and by designated time interval. In this way, the crucial events are submitted in real time, but there are also regularly scheduled checkpoints at which any important events during follow-up intervals (for example due to hospitalization elsewhere) will be captured. The first routine post-operative follow-up will be at 1 week if patients are still hospitalized, otherwise will be at the time of discharge. After discharge, the interval follow-up occurs at 1 month, 3 months, 6 months, and every 6 months for the life of the device. If the device is explanted without transplantation, the patient will be followed for one year following explant for the major events of death or transplantation.

The follow-up forms will all include information on vital signs and volume status, medications, basic laboratory values, and device settings. New York Heart Association functional status for adults and Ross Class for children will be noted. At each time interval re-assessment will be documented regarding current intent as bridge to recovery, transplant, likelihood of eligibility for

transplant, or permanent support, with a check-list of considerations relevant to that decision. When available, echocardiographic information will be included regarding function of both ventricles and atrioventricular valves. Invasive hemodynamic measurement regarding filling pressures, pulmonary pressures, and cardiac output will be included when available. The EuroQOL questionnaire and the Trailmaking assessment of neurocognitive function will be performed at pre-implant, 3 months, 6 months, and every 6 months thereafter.

Adverse Events: Data on specific adverse events will be collected by two mechanisms:

- (1) The occurrence of **infection, device failure, neurological event, and death** trigger a separate screen which will collect relevant data elements;
- (2) Other adverse events (see Appendix A for complete list) will be identified and collected through routine data acquisition at the specified follow-up intervals.

5.3 Quality of Life data

Quality of Life (QOL) will be measured by the EuroQOL sixteen-item instrument. Pediatric patients (< 18 years of age) will not be asked to complete this instrument. We anticipate that completing this instrument will take the patient 20 minutes. Administering the instrument and entering the data into the registry will require approximately 30 minutes of coordinator time. The QOL questionnaire will be completed pre-implant and post-implant (3 months, 6 months, and Q 6 months thereafter).

The EuroQOL instrument will be obtained after consent before MCS D or, if not obtainable, at the next designated time period after implantation. When able, the patients will complete the questionnaire themselves. If unable, they can answer questions read aloud by the coordinator or by a family member. The method of completion will be recorded.

After implantation, the EuroQOL will be completed as scheduled, whether the patient is hospitalized or at a clinic visit. Missing answers will be queried by the coordinator at the time of form completion. Forms missing will require a missing QOL data form. The QOL data will be entered into the electronic database and transmitted to UNOS immediately.

5.4 Neuro-cognitive data

Neurocognitive function will be measured by the Trail Making Neurocognitive Test, Part B. This test of general cognitive function also specifically assesses working memory, visual processing, visuospatial skills, selective and divided attention, and psychomotor coordination. Part B involves connecting, in alternating order, encircled numbers (1-12) and encircled letters (A-L) randomly arranged on a page. This test is scored by overall time required to complete the connections accurately. The examiner points out and corrects mistakes as they occur; the effect of mistakes, then, is to increase the time required to complete the test. This test usually takes 3-4 minutes to administer. This score will be entered directly into the web-based data entry system. Pediatric patients (< 18 years of age) will not be asked to complete this instrument.

5.5 Blood and Tissue Samples

This is a prospective program to obtain and bank intra-operative myocardial tissue and blood samples in end-stage heart failure patients receiving a MCS D at the time of device implant and explant or device exchange. Whenever possible, tissue samples (i.e. apical core or explanted heart) will be collected for pathology, immunohistochemistry, and future molecular analyses. Venous blood samples will be collected to determine neurohumoral, DNA, and serum analyses. Specific studies relating to genomics, proteomics, and structural biology will be submitted by

investigating institutions requesting tissue specimens. Investigating institutions are those which contribute blood and tissue to the INTERMACS NHLBI repository. Blood and tissue will be banked for a year before any analyses are performed.

Myocardial tissue samples and venous blood samples will be collected at time of device implant and device removal (i.e. explanted failing heart during transplant, MCSD exchange, or myocardial recovery). Please refer to the standard operating procedures (SOPs), Appendix H for Hospitals for explicit instructions for collection, on-site storage, and shipping procedures. Collected tissue and blood specimens will be stored onsite at -80 degrees Celsius or in liquid nitrogen tanks. Using pre-paid shipping labels, the site will ship the samples to the NHLBI designated repository every three patients, or every three months, whichever comes first.

Instructions on methods and procedures will be provided by the NHLBI repository, including packing materials, coding labels and preaddressed shipping labels. Batched samples will be sent quarterly (or every 3 patients, whichever comes first) directly to the address provided below and in the User's Guide. A shipping manifest will be emailed to the NHLBI repository and their 24-hour emergency contact at the time of shipment to facilitate tracking.

NHLBI repository:

SeraCare BioServices

Ms. Christine Demasco

217 Perry Parkway

Gaithersburg, MD 20877

Tel: 301.208.8100

Fax: 301.208.8829

<http://www.nhlbi.nih.gov/resources/medres/reposit/reposit.htm>

NHLBI@seracare.com and bbiotech@chemtelinc.com (24-hour emergency contact)

6.0 Analyses of Registry Data

Introduction

The value of any clinical registry lies in the statistical analyses of the data and the clinical relevance of these analyses. The registry will collect a wide array of patient, device, and follow-up information. This section outlines the general analyses and the statistical methods.

Purposes

- Summarize the characteristics of the patients who are receiving MCSDs, when (in relation to progression of disease) they are receiving MCSDs and why (bridge to transplant, bridge to recovery, destination therapy).
- Summarize the characteristics of MCSDs that are being implanted.
- Estimate the time-related distribution of post-implant adverse events.
- Determine risk factors (both patient related and MCSD related) for post implant events.
- Contribute to evidence based management of patients with MCSDs.
- Contribute to evidence based management of implanted MCSDs.
- Provide device specific analyses to aid in MCSD development.
- Evaluate safety and efficacy of MCSD implants.
- Determine the time-related costs (resource utilization) of MCSDs and the risk factors associated with increased costs.

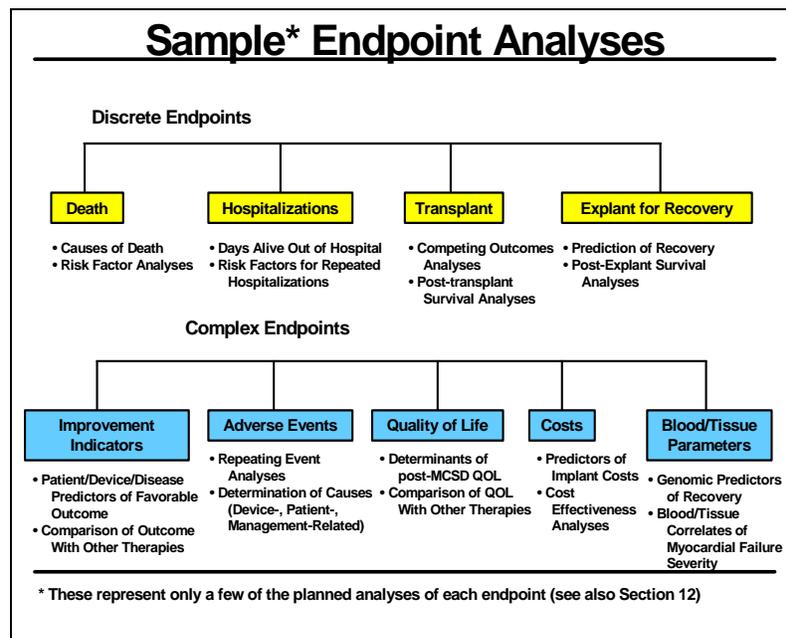
- Compare the costs resource utilization of MCS D therapy to other treatments for advanced heart failure.
- Evaluate quality of life post MCS D implant.
- Estimate changes in biological markers (derived from blood and tissue samples) from pre to post MCS D implant and relate such changes to probability of improvement in or recovery of ventricular function.
- Compare alternative therapies (MCS D, transplant, medical) for patients with end stage heart failure.
- Produce patient-specific predictions of time related outcomes to aid in clinical decision making and allocation of therapies for advanced heart failure.
- Analyze biologic markers obtained from MCS D patients as indicators of severity of advanced heart failure.

Patient Profiling

Patients who receive MCS Ds will be characterized regarding their demographic data, medical history, clinical status including descriptors of heart failure, pre-implant laboratory values and pre-implant hemodynamic data.

Primary Endpoints

The major categories of endpoints are death, transplant, explant, patient adverse events, rehospitalization, device related adverse events, change in quality of life, costs, functional status and changes in blood and tissue parameters. Each of the endpoints will be analyzed as time related events.



Transfer of data to UAB for analyses

The data will be maintained at UNOS and then transported to UAB for data analysis. Periodic transfer of SAS data sets from DCR (UNOS) to the DCC (UAB) will occur via a secure mechanism. Separate files for each registry screens will be sent as SAS datasets (SAS Institute, Cary, NC), created through SAS version 9.1. Merging of the files, based on unique patient identifiers, will occur after transfer. The DCC will receive a limited access data file.

Analytic Methods

Statistical analysis of the MCSD will require a variety of methods including analysis of variance, multiple linear regression, t-tests, chi-square tests of association, correlations, and descriptive statistics. The group of methods generally labeled survival analysis techniques will be the methods most used. In general, survival analysis refers to all methods applicable to time-related events or outcomes. Most of the outcomes that will be documented in the MCSD registry will have time components. For example, time-until-death, time-until-transplant, time-until-infection, time-until-device-malfunction are all events that will have an associated interval post implant. However, additional analytic methods will be necessary for issues such as costs and quality of life.

The Hazard Function

The time-related survival methods will combine more traditional non-parametric or semi-parametric methods with parametric hazard function analysis. Kaplan-Meier non-parametric estimation provides estimates of time-related freedom from an event. While the depiction of these estimates is useful, parametric estimation using hazard models can offer more insight into the timing of an event. The hazard function is the instantaneous (or daily) rate of an event. This function can depict time periods of high risk for an event and can estimate whether the risk is increasing, decreasing or peaking.

Parametric hazard estimation will employ simple to complex hazard models depending on the distribution of the event. Both the parametric survival function and the corresponding hazard function will be displayed to provide a complete description of the event.

Competing Outcomes

Depictions of a single time-related event do not take into account other events. For example, a depiction of death would assume that transplantation does not exist. Patients are censored at time of transplant. If informative censoring does not exist (i.e. if patients are not transplanted due to impending death but instead selected at random for transplant), then the depiction can be thought of as the natural history of mortality after device implant. In reality, this rarely occurs, since patients are usually selected at a given time because of medical necessity. This informative censoring complicates the interpretation of this single event depiction.

Alternatively, one may wish to estimate the simultaneous time-related probability of mutually exclusive events. Competing outcomes estimation allows the time related probability of actually experiencing each of these events. At any point in time, a patient has either experienced one of the three events or he/she is alive and waiting for one of the events to occur. A probability can be assigned to each of these four possible states and the sum of the four probabilities will be equal to one at each point in time. The non-parametric estimation of these probabilities is an adaptation of the Kaplan-Meier method. In the standard use of the Kaplan-Meier methods, event probabilities are accumulated across time. In competing outcomes analysis, the combined event is analyzed and then probabilities are accumulated separately according to which event occurred.

Multivariable risk factor analysis

The most common multivariable method for identifying risk factors is Cox proportional hazard regression. This method assumes proportional hazards for different levels of a potential risk factor. The p-value results from testing the null hypothesis that the proportionality parameter is equal to one. The method is often called a semi-parametric technique because it does not require or estimate the form of the underlying parametric hazard. It only requires (assumes) that hazards for different levels of risk factor are proportional across time. This assumption is often incorrect. The magnitude of the effects of the final risk factor model from Cox regression is not easily displayed due to the lack of a specified hazard model. This also prevents a simple, continuous depiction for a specific patient with his unique values of the risk factors.

Consequently, we have pursued a parametric version of survival regression that builds on a framework of hazard functions. The concept is still proportional hazard regression, but the hazard function is estimated and decomposed into additive phases. Each phase is then constructed to be a function of the risk factors. The model of risk is then totally specified as a mathematical equation that can be “drawn” for any time period and any specified set of risk factors. This system also allows the identification of risk factors that impact different phases of risk.

Predictions

This ability to produce time-related expected survival for a specific patient (with his/her specific risk profile) is one of the strengths of parametric hazard analysis. The predictions are a function of the estimated hazard functions and the identified risk factors. The hazard function and risk factors are derived from the actual data.

Repeated events (Adverse events)

Most adverse events can occur more than once. For example, once a patient experiences an infection episode, he remains at risk for another episode. These repeating events require methods that are an expansion of the previously described methods.

First events analysis

The first occurrence of an event can be analyzed exactly as a terminating event such as death (see previous discussion). While this analysis does not appear very useful clinically for events that recur frequently, it does provide a time-related estimate of the proportion of patients who have remained free of the event.

The FDA approach

Most of the medical device guidance documents from the FDA for analyzing events that can happen multiple times specify a specific analytic approach. First a calculation of the percent of patients who experience at least one event during the first 30 days post implant is presented. Next, a linearized rate is calculated for events that occur after the first 30 days. Summing all of the post 30-day events and dividing by the total patient follow up intervals after 30 days calculates this. The rate is usually multiplied by 100. The calculation is then the number of events that are estimated to occur in 100 years of follow up. This is a useful calculation but it assumes a constant hazard rate across time. For many events, for example device malfunction, this may be an incorrect assumption.

Parametric hazard approach

The parametric hazard methods can be applied to multiple events. This allows the estimation of the shape of the underlying hazard and specific statistical testing for an increasing hazard or decreasing hazard or peaking hazard. This approach will allow detection of device related events whose occurrence rate is rising to unacceptable levels at some point in time.

Cumulative event estimation

Another useful display of repeated events depicts the accumulation of events that will occur, on the average, for a single patient. This method of depiction illustrates the rate of accumulating events as a function of time.

Modulated Renewal

Another method of analyzing repeated events is the modulated renewal method. In this approach, the unit of observation is each episode of an event. a patient is tracked from time of device implant until he experiences his first event. he is then re-entered into the analysis, with a new starting time and is tracked until his next episode. This process is continued for event re-occurrences. The analysis of this data structure is then performed in the parametric hazard domain and is particularly amenable to risk factor analysis that incorporates the event history of a patient when predicting his next occurrence.

Each of these methods for repeated adverse events contributes to the understanding of the time course of the event and the related risk factors. The methods will be particularly helpful in calculating the time related risk of device related adverse events.

Planned Analyses

Patient Characteristics

Patients who receive MCSDs will be summarized regarding their demographic data, medical history, and clinical status including descriptors of heart failure, pre-implant laboratory values and pre-implant hemodynamic data. Novel aspects of the registry include the establishment of 7 INTERMACS profiles that will describe the clinical severity of disease at the time of implantation. This will facilitate risk stratification for outcomes, and advance the selection of patients who have sufficient severity of disease to warrant MCSDs but less severe decompensation to compromise the peri-operative outcome. (Data will be summarized by frequencies, measures of central tendencies, measures of dispersion, cumulative distribution functions, graphical displays, cross tabulations and correlations). An additional component is the ongoing evaluation of patients with regard to evolving eligibility for transplantation and explantation in order to better understand the factors leading to transplantation or explantation. Subsequent tracking of patients will allow the decision process to be continually refined for better outcomes.

Data will be summarized by frequencies, measures of central tendencies, measures of dispersion, cumulative distribution functions, graphical displays, cross tabulations and correlations.

MCSD Characteristics

MCSDs that are implanted will be summarized according to their physical and physiologic characteristics (e.g. size, weight, pulsatile or continuous flow, range of flow rates, etc.) and their initial flow settings. The Industry Subcommittee will assist in selecting variables for analysis that are relevant to emerging technologies.

Survival

The analysis of post implant survival will utilize all of the methods outlined in the previous section. The emphasis will be on the time related pattern of overall death and each of the causes of death. The investigation of risk factors, especially those risk factors which can be modified for a patient, will be a priority.

Transplantation

Time to transplant will be analyzed similarly to survival. In addition to the examination of patient risk factors and device factors which predict survival to transplant, the prolonged implant duration in many "bridge" patients awaiting a suitable heart donor will facilitate analyses that give insight into longer-term "destination" therapy.

Adverse Events: Patient and Device Related

A key feature of the entire registry analysis will be the examination of the time course and risk factors for all of the possible patient related and device related adverse events. We will use the methods listed under Analytic Methods to evaluate these interactions.

Competing Outcomes

The major events that "compete" for a patient are death, transplantation and recovery. The simultaneous time-related estimation of the probability of these events will be depicted. Separate risk factor analyses will be performed for each individual outcome event.

Quality of Life (QOL)

Paired t-tests will test for changes in pre-implant and follow-up interval measures. Multiple linear regression will be used to identify patient groups who have the least and the greatest improvement in quality of life. Analyses will focus on the impact of MCSD therapy on QOL indicators, comparisons with QOL after transplant and other therapies for advanced heart failure (through published studies or parallel patient cohorts).

Analysis of Tissue and Blood Samples

Tissue and blood data will be analyzed to characterize patients who are receiving MCSDs and to examine changes in this data from pre-implant to explant. Standard statistical techniques for assessing changes across time will be employed. The pre-implant blood and tissue data will be part of the risk factor analyses to assess factors associated with the outcome endpoints.

Costs

Multivariate statistical techniques, most often regression analysis, are used to investigate relationships among the variables of interest. Analytical emphasis will be on resource utilization.

Analysis of MCSD Efficacy

In all of the analyses for death, transplant, recovery, adverse events, quality of life, tissue and blood variables, and costs, we will investigate the effects of device characteristics (pulsatile flow, size, etc) on outcome. A major focus of INTERMACS will be the identification of the strengths and weaknesses of the different devices for specific patient subsets and facilitation of the evolution of MCSD technology.

Evaluation of Hospital Outcomes

Each hospital that contributes data to INTERMACS will be periodically evaluated for their outcomes. The basis of the evaluation will be risk-adjusted comparisons using the results of the multivariable analyses. The observed survival, depicted by a Kaplan-Meier, is also depicted. The observed and expected deaths will then be statistically compared where the patient-specific risk factors and length of follow-up are explicitly incorporated into the comparison.

Additional Analyses at Participating Centers

In addition to the site-specific information provided routinely, qualified centers in good standing regarding data contribution may consider applying to receive an aggregate registry dataset with identifiers removed, for specific planned analysis as approved by the Operations Committee.

7.0 Periodic Statistical Summaries

7.1 National Heart Lung and Blood Institute (NHLBI)

Monthly Reports shall include:

- Patient recruitment in various categories
- Hospitals providing the data
- Status of follow-up data collection
- Data analysis
- Problems encountered, if any
- Quality of data received

Quarterly Progress Reports shall include:

- Documentation and summarization of all work results for the quarter, specifically:
 - Patient enrollment activities
 - Quality of data and specimens collected
 - Evaluation of performance of the hospitals
 - Forms completion rates

- Response variables and adverse events
- Each report shall identify the number of patients enrolled by participating hospital, MCSDs that were implanted, and describe significant patient outcomes
- Brief overview of any problems that occurred during the current reporting period and their resolution or status
- Summary of activities planned for the next reporting period
- Listing of the manuscripts and publications resulting from the work of the Registry
- Any research protocols from outside researchers who will be using MCSD Registry data

Abstracts and Manuscripts shall be provided within 30 days of publication

Final Report shall include a summation of the work performed and results achieved for the entire contract period. The report shall be prepared in the format described for Quarterly Progress Reports and be in sufficient detail to describe comprehensively the results achieved. The report shall also include a plan for future long-term support of the Registry through additional funding sources other than the Government. The Final Report shall be submitted on or before the last day of the contract performance period and shall be in sufficient detail to serve as a reference document.

7.2 Centers for Medicare and Medicaid Services (CMS)

CMS will receive copies of the NHLBI reports along with any specific reports that they may require (no patient-specific data will be given).

7.3 Food and Drug Administration (FDA)

FDA requires user facilities, such as a hospital, to report all serious injuries or deaths associated with a medical device to the FDA within 10 days of their occurrence. This is known as an MDR (Medical Device Report). The registry will assist the hospitals in fulfilling this regulatory requirement.

Additionally, reports to FDA could inform:

- (1) Objective performance criteria: Randomized trials of IDE MCSDs may not be practical. The FDA will often allow single arm studies where the results from a medical device are compared with objective performance criteria (OPCs). These OPCs are derived from the literature or existing databases. The MCSD Registry can be used to generate OPCs for the major safety endpoints after MCSD implant.
- (2) Unexpected risks: The MCSD registry can be analyzed to identify MCSDs with unexpected risks for major safety events.

7.4 Industry

Quarterly reports will be provided to each manufacturer of MCSDs that are entered into INTERMACS. A specific manufacturer will receive no information about any MCSDs from other manufacturers. The reports will provide statistical summaries of patient demographics and clinical characteristics at the time of implant. Adverse event rates, including death and explant, will be calculated according to post-implant time period. Pump flow characteristics will also be described according to post-implant time period.

7.5 Individual Sites

Quarterly reports will be provided to each participating site. A specific site will receive no information about any other site. These reports will be similar to the industry reports except that they will describe a site's experience instead of the experience with a specific MCSD.

7.6 Observational Study Monitoring Board (OSMB)

The OSMB will receive copies of the NHLBI reports along with any specific reports that they may require.

8.0 Quality assurance

Data Quality

The United Network of Organ Sharing (UNOS) will act as [the Data Collection Repository](#) for INTERMACS. UNOS will continually evaluate data quality and completeness through consistency checks at data entry, periodic data reports to the sites, and audits. The DCC will examine data quality prior to each analysis. The focus will be on completeness of periodic follow-up and also on identifying impossible or improbable combinations of variables. All questionable data points will be referred to UNOS for verification. The DCC will make no changes to the data; only UNOS will make corrections to the original data files.

Data monitoring and checks for inconsistencies

The database will be subject to analytical quality assurance audits following the completion of data entry. Depending on the types of discrepancies identified, UNOS and DCC staff members will contact participating centers to resolve these issues. Resolution may be accomplished via telephone contact, e-mail or hard copy mailings. The discrepancies and their resolutions will be tracked for future reference and further review. Based on a review of the results of the analytical QA processes, additional items may be incorporated into the QA process at the Steering Committee's request. Participating centers will be able to review and modify previously submitted data at any time. Additionally, summary screens and reports of patients and devices reported, current patient status, most recent reported event and other data will be available to the member institutions to assist the institution in assessing the completeness of reporting. UNOS will employ established standard operating procedures and work instructions for all applications used to maintain the quality of INTERMACS data. These procedures and instructions will be used in completion of all data maintenance activities associated with the MCSD. Work instructions will provide step-by-step directions for processes involved in data maintenance, and internal audits will ensure compliance with these standards and instructions.

Event Adjudication

The Adjudication Committee will be comprised of the Adverse Event subcommittee. There will be a pediatric cardiovascular physician included. Industry representatives will not be included in the Adjudication Committee. The chair of the Adverse Events Committee will be the chair of the Adjudication Committee. The function of the Adjudication Committee is to review all adverse events and deaths. They will make final decisions regarding causes of death, device failure categories, validation of an adverse event, and any other relevant variables concerning death and adverse events. The Adjudication Committee will meet quarterly. The DCC will facilitate the functions of the Adjudication Committee by scheduling meetings and providing the necessary data for the adjudication process.

Requirements for Centers

Each participating hospital shall: (1) have at least one person complete training, (2) provide dated proof of initial and annual IRB approval, IRB approved Informed Consents and proof of Human Subjects Training for the principal site staff (to include the Principal Investigator, Co-Investigators and Site Coordinator), (3) enter complete follow-up data on all consenting patients, (4) submit to regular and “for cause” data audits by UNOS (5) correct identified errors in a timely fashion.

Training for Centers

Net Meeting will be used to conduct training meetings on an ongoing basis. Net Meeting is a secure, subscription-based service that allows for meetings and their related documents to be conducted in a virtual electronic environment. These meetings can be linked to conference calls and recorded for future use. Net Meeting allows participants to collaborate on documents and view another participant's desktop. For example, trainers can run a Net Meeting and enable participants to view his or her desktop. Attendees can follow along as the trainer shows step-by-step instructions. This system will enable users to take online exams as well as enable UNOS to capture exam results, track and report certifications and help users identify areas of improvement.

Assistance to centers

A **Comprehensive User Guide** will provide step-by-step instructions for using the system and will include definitions for all fields collected in the system. The Guide will also identify main processes in the application and explain proper protocol and standard procedures for data and specimen collection. This Guide will support and reinforce topics in the manual of operations.

A **help desk** will be available to provide support. Help desk personnel are available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern Standard Time (EST). They will assist users of the system with questions and difficulties using the system. Participating center users can call in to report inconsistencies and ask questions concerning the data entry process. Additionally, participants can e-mail their questions and concerns 24 hours a day, seven days a week. An initial response will be made to all inquiries within two business days. Resolution of issues, not related to the application, will be completed within two business days of the initial response. Calls that require changes to the MCSD Registry may take longer to resolve. The details of each call and corresponding resolution are logged in a database and tracked. The help desk database is monitored routinely to achieve ongoing improvements in the application and to enhance participant service and satisfaction.

Site Visits/Audits

The audit process for INTERMACS will include visits to all participating centers. Annual audit visits will begin in year 2 and proceed each consecutive year, through and including year 5. Twenty-five percent of all participating centers will be audited within each calendar year. As participating centers sign on to the Registry, they will be assigned an audit year based on geographic region and anticipated number of device implantations. The schedule has been devised so that all regions and all volume categories are represented in audits during each audit year. For those registry participants that have cumulated up to and including 20 patients by their assigned audit year, all patient records will be audited. For those registry participants that have cumulated in excess of 20 patients by their assigned audit year, a random sample totaling 20 patients records will be audited. Audited data will include key data fields, as determined by the DCC in consultation with the Steering Committee. Audit visits will monitor data accuracy of web based data submissions and information contained in source documents as well as

participant performance and progress. "For Cause" audit visits will be made as indicated by the Operations Committee. All audit results will be reported to the Operations Committee.

The audit process will identify member institutions that perform poorly in data submission compliance. The UNOS staff will identify and work with these underperformers to identify reasons for low rates of data collection and/or tardy data submission. These institutions will be retrained on proper data collection methods with the goal of identifying and overcoming obstacles to submission.

Appendix IV

INTERMACS Site User's Guide



B. SITE USER'S GUIDE

This Site User's Guide will provide the necessary information for site enrollment, IRB approval, informed consent and web-based data entry.

1.0 Introduction

2.0 Frequently Asked Questions

- What is INTERMACS?
- Who sponsors INTERMACS?
- What are the benefits of participating in INTERMACS?

3.0 Site Eligibility and Enrollment

4.0 Participation Requirements

- 4.1 IRB approval/Federal Wide Assurance Number
- 4.2 Participation Agreement
- 4.3 Financial Disclosure and Conflict of Interests
- 4.4 Training
- 4.5 Certification and Audit Process
- 4.6 Human Subject Training

5.0 Web-based Data Application

- 5.1 Introduction
- 5.2 System Security
- 5.3 Forms
- 5.4 Inclusion/Exclusion Criteria
- 5.5 Entering a New Patient
- 5.6 Editing an Existing Patient
- 5.7 Follow up
- 5.8 Adding an Event
 - 5.8.1 Adding a Device
- 5.9 Ending Patient Participation

6.0 Data Dictionary

- 6.1 Demographics Form
- 6.2 Pre-Implant Form
- 6.3 Implant Form
- 6.4 1 week and 1 month post implant Form
- 6.5 3 month and 6 month follow up Form
- 6.6 Implant Discharge Form
- 6.7 Rehospitalization Form
- 6.8 AE Device Malfunction Form
- 6.9 AE Infection Form
- 6.10 AE Neurological Dysfunction Form
- 6.11 Explant – Transplant Form
- 6.12 Death Form
- 6.13 Quality of Life Questionnaire
- 6.14 Neurocognitive Function Test
- 6.15 Blood and Tissue Specimens (optional)
- 6.16 Adverse Event Reminders

B. SITE USER'S GUIDE

1.0 Introduction



Dear Hospital VAD Team,

Welcome to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)! We are pleased that your hospital will become part of the INTERMACS collaboration. This User's Guide will provide you all the necessary information for site enrollment, IRB approval, informed consent and web-based data entry.

INTERMACS is a unique national collaboration of the National Heart, Lung and Blood Institute, the Food and Drug Administration, the Center for Medicaid and Medicare Support, clinical sites, MCSD professionals and industry. The United Network for Organ Sharing will provide the web-based data entry system and the University of Alabama at Birmingham will serve as the data collection and analysis center.

The main purpose of INTERMACS is to improve patient outcome by advancing the clinical application and science of mechanical circulatory support. Ultimately patients will have the primary benefit from INTERMACS. However, there are also several immediate benefits to the local hospital. Among these is the fact that INTERMACS fulfills the requirement by CMS that data from all destination VADs be entered into a national database. We also believe that INTERMACS will serve as an easily accessible summary of the important events in a patient's post implant clinical course.

We look forward to this collaborative effort with your hospital. Please feel free to contact us with any questions about any part of INTERMACS.

Sincerely,

A handwritten signature in black ink, appearing to read "James B. Young".

James B. Young, MD
Study Chair
Cleveland Clinic Foundation

A handwritten signature in black ink, appearing to read "James K. Kirklin".

James K. Kirklin, MD
Principal Investigator
University of Alabama at Birmingham

A handwritten signature in black ink, appearing to read "Lynne Warner-Stevenson".

Lynne Warner-Stevenson
Co-Principal Investigator

A handwritten signature in black ink, appearing to read "Bob Kormos".

Bob Kormos
Co-Principal Investigator

A handwritten signature in black ink, appearing to read "Patrice Nickens, M.D.".

Patrice Nickens
NHLBI Project Officer

2.0 Frequently Asked Questions

What is INTERMACS?

The **Interagency Registry for Mechanically Assisted Circulatory Support**, or INTERMACS, is a national registry for patients who are receiving mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives.

Who sponsors INTERMACS?

This project has been funded in whole or in part with federal funds from the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), and the Department of Health and Human Services (HHS) under Contract Number N01-HV-58198.

The University of Alabama at Birmingham (UAB) is the Data Coordinating and Data Analysis Center and United Network for Organ Sharing (UNOS) is the Data Collection Repository with responsibility for maintaining the database.

What are the benefits of participating in INTERMACS?

Participation in INTERMACS meets the CMS (Centers for Medicare and Medicaid Services) reporting requirements as stated below:

CMS National Coverage Determinations, 20.9 (Revised 3/27/07)

...Naming the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) as the registry that satisfies the CMS reporting requirement...

Participation in INTERMACS meets the JCAHO (Joint Commission on Accreditation of Healthcare Organizations) reporting requirements as stated below:

Proposed LVAD Certification Requirements from JCAHO

“The joint commission criteria include standards requiring facilities to participate in a national, audited registry which we have identified as INTERMACS. Therefore, this requirement is equal to the CMS facility requirement regarding INTERMACS participation.”

Participation in INTERMACS will require inclusion of *all* consented patients implanted with FDA approved devices designed for chronic implantation, regardless of initial

intent. INTERMACS is designed to simplify reporting of essential outcome data and to provide center-specific analyses for quality improvement.

3.0 Site Eligibility and Enrollment

3.1 Eligibility

Any medical center in the United States that has an active ventricular assist device therapy program is eligible to contribute to INTERMACS.

3.2 Enrollment

Registry enrollment must be completed online at <https://www.intermacs.org/enrollment>. Please select the [guidelines](#) link and follow the simple steps provided to enroll your facility and personnel in INTERMACS.

1. Enroll your medical center by completing the **Hospital Information** format.
2. Assign your staff roles for participation in INTERMACS and complete the **Personnel Contact Information** format.

In order to complete the enrollment process, you must assign the following roles to qualified personnel at your medical center:

- **Local Principal Investigator (PI)**, responsible for oversight of data submissions and registry compliance
- **Site Administrator**, to act as “point person” for data related inquiries, receipt of reports and audit coordination
- **Lab Data Coordinator**, responsible for oversight of the collection, preservation, packaging, transport and documentation regarding blood and tissue specimens (should your center elect to participate in the blood and tissue program).

4.0 Participation Requirements

Before you begin entering patient data into INTERMACS, your medical center must complete steps 1 through 6:

Step 1: IRB Approval/Federal Wide Assurance Number

Step 2: Participation Agreement

Step 3: Financial Disclosure and Conflict of Interest

Step 4: Training

Step 5: Certification

Step 6: Human Subject Training

Note: If your medical center optionally elects to participate in the Blood and Tissue portion of INTERMACS, Blood and Tissue certification must be completed.

4.1 Step 1 – IRB approval

IRB Guidelines for Sites are provided in **Appendix B**.

Informed Consent Templates and Required Elements are provided in **Appendix C**.

Your hospital's **Institutional Review Board (IRB)** must review this registry before you will be permitted to submit patient data to INTERMACS. Enclosed are guidelines for your medical center's submission of an application to participate in INTERMACS (Appendix B). If your IRB approves your application for participation in this registry, you must submit documentation of that decision along with the Federal Wide Assurance Number to INTERMACSSupport via fax (804-782-4809) or mail:

INTERMACS Coordinator
UNOS Data Management Services, Room 4147
700 North 4th Street
Richmond, VA 23219

Your center will not be activated in INTERMACS until IRB approval has been submitted. Documentation of renewal of your center's IRB approval and Federal Wide Assurance Number must be submitted to the INTERMACS Coordinator at the address or fax number above.

Please note: Your Institutional Review Board must approve your participation in INTERMACS even if your center has already been approved to participate in the ISHLT MCSD Database. The databases are very different in both the time points for reporting and the scope of questions.

Please follow your institution's guidelines for obtaining patient consent for participation in INTERMACS. **It is strongly recommended that patient consent be obtained pre-implant.**

Ten sample templates are included for your reference in Appendix C:

- Patient Consent for Participation in Research
- Parent Consent for Child's Participation in Research
- HIPAA Authorization for Release of Information (Adult)
- HIPAA Authorization for Release of Information (Pediatric)
- Patient Consent for Participation in Blood and Tissue Repository
- Parent Consent for Child's Participation in Blood and Tissue Repository
- Revoke Authorization for Participation in Research (Adult)
- Revoke Authorization for Participation in Research (Pediatric)
- Revoke Authorization for Participation in Blood and Tissue Repository (Adult)
- Revoke Authorization for Participation in Blood and Tissue Repository (Pediatric)

Your facility is responsible for obtaining and maintaining all patient consents and all IRB documentation. Documentation of IRB status and patient consents are subject to INTERMACS audit.

4.2 Step 2 – Participation Agreement

The **Participation Agreement** is provided in **Appendix D**.

The Medical Center Agrees to:

- Submit application to local IRB for approval of participation in INTERMACS
- Center agrees to submit to INTERMACS in a timely manner all requested data for all patients at the center who receive a MCSD.
- Center understands that incomplete data submissions or submissions on partial patient populations entitle INTERMACS, at its discretion, to discontinue Center's participation in the database and Center's access to the collected data.
- Center agrees to designate a Principal Investigator and appoint a Site Administrator as the designated contact for INTERMACS communications and will maintain current mail, phone, and fax and email contact information for those individuals.
- Center agrees to notify INTERMACS in the event of any change in the Principal Investigator and/or Site Administrator for the database.
- Center assumes responsibility for maintaining security of its assigned login names and passwords.
- Center agrees to provide INTERMACS with documentation verifying that the Center's Institutional Review Board (IRB), Privacy Board, or equivalent has approved the Center's participation in this database and the Center must provide the Federal Wide Assurance Number. If Center is approved for exemption, written notification must be provided to INTERMACS.
- Center agrees to abide by all HIPAA regulations when reporting data to INTERMACS. Specifically, Center must ensure that it obtains a signed HIPAA Authorization from each individual that authorizes the release of their personal health information to INTERMACS for the uses described above; or, that the IRB has waived the requirement for the individuals to sign a HIPAA authorization. By signing this Participation Agreement, Center certifies that it will obtain HIPAA authorization from the patients, or, that it will obtain an IRB waiver of the HIPAA authorization requirement.

INTERMACS Agrees to:

- INTERMACS assumes all responsibility for maintaining security of its data collection and storage systems.
- INTERMACS agrees to provide Center with bi-annual reports of center-specific data and aggregate data beginning July 2006, or as soon thereafter as practicable.
- INTERMACS grants Center permission to submit data analysis requests to the INTERMACS Steering Committee for consideration beginning January 2007.
- INTERMACS agrees to publish an annual report of all aggregate data and a listing of all centers participating in the Registry.

Before you may begin entering data in INTERMACS, your Program Director is required to sign the INTERMACS Participation Agreement (Appendix D).

Please print it and submit the signed contract to INTERMACSSupport:

INTERMACS Coordinator
UNOS Data Management Services, Room 4147
700 North 4th Street
Richmond, VA 23219

Or via fax: (804) 782-4809
Attention: INTERMACS Coordinator

4.3 Step 3 – Financial Disclosure and Conflict of Interest

The Financial Disclosure and **Conflict of Interest documents** are provided in **Appendix E**.

Before you begin entering patient data in INTERMACS, your Principal Investigator and Co-Investigator are required to complete the **Conflict of Interest Disclosure Form**. The Conflict of Interest Disclosure Form can be found at Appendix E.

Please print it and submit the signed statement to INTERMACSSupport:

INTERMACS Coordinator
UNOS
Data Management Services
700 North 4th Street
Richmond, VA 23219

Or via fax: (804) 782-4809
Attention: INTERMACS Coordinator

Your center's Principal Investigator and Co-Investigator must renew the Conflict of Interest Disclosure statement by completing, signing and submitting the **Conflict of Interest Disclosure Form** annually.

4.4 Step 4 – Training

Before entering patient data in INTERMACS, your center must complete the online INTERMACS training by going to www.intermacs.org and clicking on "INTERMACS Membership" to complete this process.

For more information, please contact Molly Massey, INTERMACS Registry Lead at 804-782-4077 or masseymb@unos.org or you may contact INTERMACSSupport at support@intermacs.org.

4.5 Step 5 –Certification and Audit Process

To enter patient data, a medical center must be **certified** by INTERMACS to participate in the Registry. Certification requires that your medical center:

1. Maintain an **active MCSD Program**
2. Employ **experienced professionals** in MCSD therapy
3. Provide **personnel and facilities to record and transmit data**
4. Provide **personnel and facilities to collect, preserve package and transport biological specimens** (should your center elect to participate in the blood and tissue program)

To MAINTAIN CERTIFICATION, a site must

5. Maintain annual IRB approval and Federal Wide Assurance Number
6. Maintain annual Conflict of Interest disclosure
7. Maintain Human Subjects Training
8. **Correct UNOS-identified errors** in INTERMACS
9. **Respond to queries** from INTERMACSSupport
10. Participate in **annual meetings**
11. Comply with **data submission requirements** outlined in the study protocol

To ensure compliance with certification standards, an audit process has been developed. The audit process for the INTERMACS includes on site visits to all certified medical centers implanting MCSD's. Medical center participants throughout the United States will be assigned to one of four geographic regions as designated below.

Participating medical centers will be assigned an audit year based on geographic region and anticipated number of device implantations. Annual audits visits will begin in Year 2 and will proceed each consecutive year, through and including Year 5. Twenty five percent of all participating centers will be audited within each calendar year. The schedule has been devised so that all regions and all volume categories are represented in audits during each audit year.

REGION 1 – North East Region

Maine	New York
Massachusetts	Pennsylvania
Rhode Island	Ohio
Connecticut	West Virginia
New Jersey	Delaware
Maryland	New Hampshire
Vermont	

REGION 2 – Southern Region

Virginia	Louisiana
North Carolina	Mississippi
South Carolina	Arkansas
Georgia	Tennessee
Florida	Kentucky
Alabama	Washington, DC

REGION 3 – Central Region

Michigan	Montana
Indiana	North Dakota
Missouri	Minnesota
Kansas	Iowa
Nebraska	Illinois
South Dakota	Wisconsin

REGION 4 – Western Region

Washington	Colorado
Oregon	Oklahoma
Nevada	Texas
Idaho	New Mexico
Wyoming	Arizona
Utah	California
Alaska	Hawaii

Audited data will include key data fields. Audit visits will monitor data accuracy of web based data submissions and information contained in source documents. For INTERMACS participants that have entered up to and including 20 patients by their assigned audit year, all patient records will be audited. For those registry participants that have entered in excess of 20 patients by their assigned audit year, a random sample totaling 20 patients records will be audited.

All audit results will be reported to the Principal Investigator. Additionally audit results will be evaluated to renew the medical center program eligibility.

4.6 Step 4 – Human Subjects Training

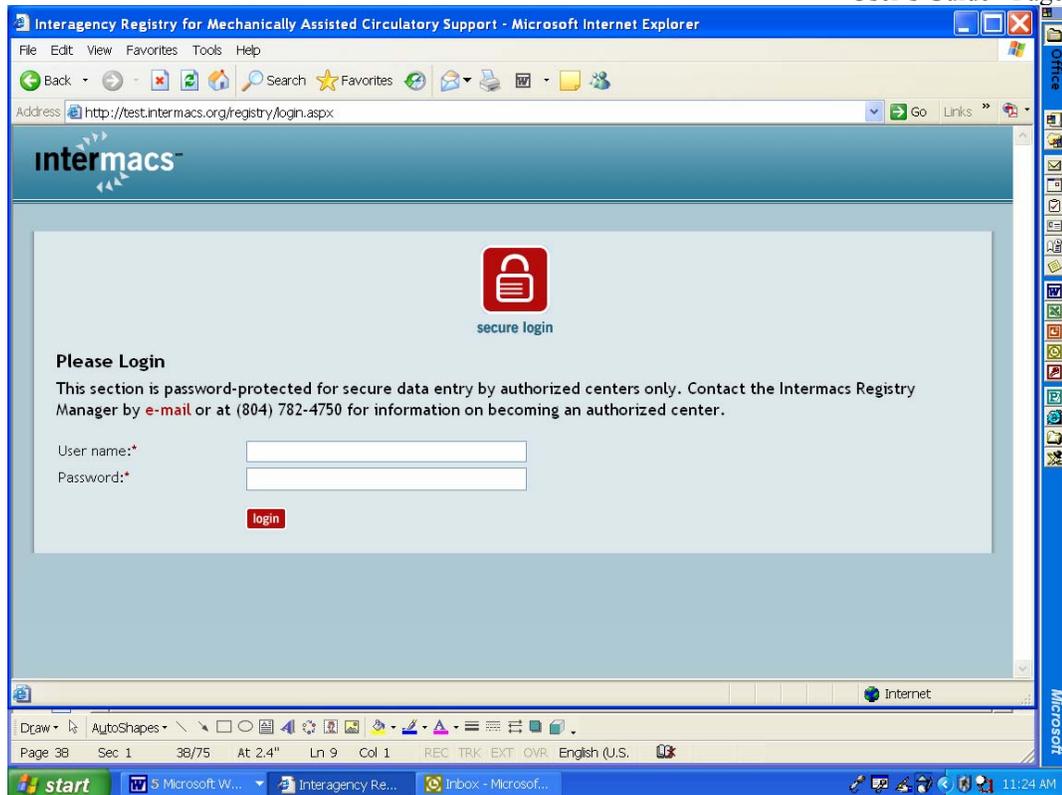
Before entering patient data in INTERMACS, all staff members must complete Human Subjects Training and provide a copy of certification to **INTERMACSSupport at support@intermacs.org** or via fax:(804) 782-4809 Attention: INTERMACS Coordinator

5.0 Web-based Data Application

5.1 Introduction

All data will be entered through the INTERMACS web-based data entry system at www.intermacs.org (select 'Patient Data Entry' to get to the secure login page below). The system is prospective and the forms should be filled out as the implant, follow-up dates, and events occur.

Users will be issued a user name and password to be used on the secure login page (see example below).



5.2 System Security

The database and web servers reside in an environment that provides multiple layers of physical and systems security. INTERMACS is fully compliant with the Security Act of 2002 and the Federal Information System Management Act. Regular audits take place to verify compliance.

Systems security is deployed with third party software and hardware, strict adherence to policy, and regular verification and auditing. The servers that host the web applications are built within the Windows 2003 framework. They follow Microsoft's best security practices and group policy recommendations from the National Institution for Standards in Technology (NIST).

Each server is monitored 24x7 for both intrusion and vulnerabilities by an integrated third-party software package. Microsoft's SMS 2003 (Systems Management Server) is used for deploying any system patches in accordance with security policies. The network is also protected by an automated anti-virus retrieval and deployment system.

Firewall software prevents hacking, virus, and other security risks from the outside. Internally, the servers reside on a segmented part of the VLAN that is isolated from the rest of the network protecting it from any adverse internal forces. All server access requires use of second level authentication for administrative access. Regular internal and external penetration and vulnerability tests are conducted by third-party contractors to determine any weaknesses in the network.

5.3 Forms

The data to be collected are divided into forms that correspond to the clinical time course of the patient. The Data Dictionary for these forms is found in Section 6.0 of this manual.

Clinical Data

Demographics

Implant

1 month post-implant

6 month follow up

Rehospitalization

AE Infection

AE Device Malfunction

AE Neurological Dysfunction

Pre-Implant

1 week post-implant

3 month follow up

Discharge

Explant

Death

Quality of Life Data

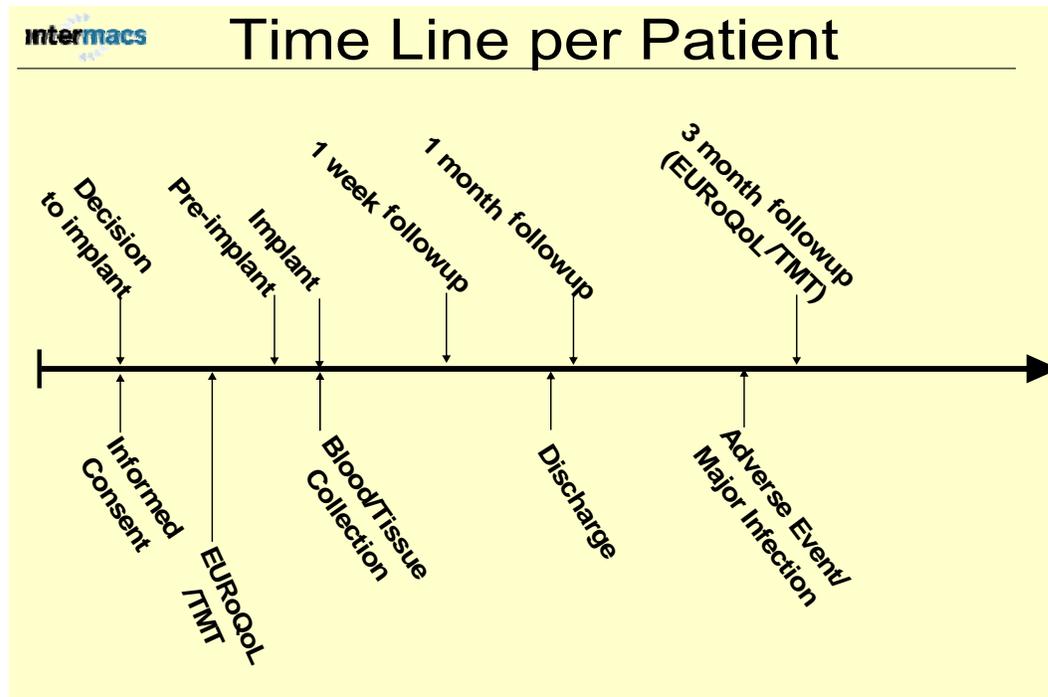
EuroQOL questionnaire

Neurocognitive Data

Trailmaking Part B neurocognitive test

Blood and Tissue Specimens

Optional



5.4 Inclusion/Exclusion Criteria

Scope

The scope of INTERMACS encompasses those patients receiving mechanical circulatory support devices (MCS) for whom discharge from the hospital is feasible. These devices are defined to be “durable” devices. There is no exclusion for age, gender, race, or ethnicity.

Inclusion Criteria

All patients with a MCSD implanted on or after 3-1-2006 will be included whether it is their 1st, 2nd, or 3rd device. The Registry will include every consented patient who receives an eligible MCSD (as listed below) at a participating center, regardless of reason: **bridge-to-recovery, bridge-to-alternative bridge, bridge-to-clinical improvement for transplant eligibility, bridge-to-transplant, or destination therapy.**

Included patients:

- 1) Patients who receive a durable mechanical circulatory support device (MCSD) which is FDA approved.
- 2) Patients who receive an MCSD after the hospital is activated (i.e., has received local IRB approval and has gained access to the INTERMACS database). Patients who received an MCSD after March 1, 2006 and before the hospital activation date, IF the local IRB allows this inclusion criterion.
- 3) Patients who have signed informed consent for the registry.

Exclusion patients:

There is no exclusion for age, gender, race, ethnicity, or any other demographic limit.

Excluded patients:

- 1) Patients who are Incarcerated persons (prisoners).
- 2) Patients who fulfill the eligibility criteria but are part of an FDA pre-approval study (these patients will be entered into the clinical trial database that is maintained by the device manufacturer).

Although no distinction is made between adult and pediatric patients in INTERMACS, additional data is requested for pediatric patients (<19 years of age) and for adult patients with congenital diagnoses. These data elements have been framed in red boxes. For adult (non-congenital) patients, you will not see these data elements.

Once a patient is entered as a pediatric patient, the patient will remain in pediatric status until the implanted device is explanted.

Please refer to the INTERMACS Protocol 3.1 'Patient Eligibility' and Appendix K. 'Device Brand List' for further information. These documents are available online at www.intermacs.org and selecting "All Things INTERMACS" – "Manuals".

5.5 Entering a new patient

The INTERMACS Eligibility forms appears when entering a new patient for the first time into INTERMACS:

INTERMACS Eligibility



Please submit the data below to confirm eligibility for INTERMACS inclusion. Only enter information on consented patients with FDA approved durable (potential for patient discharge) devices. FDA approved temporary devices should be included only if they are implanted simultaneously with a durable device or subsequent to a durable device.

Note: If a patient is part of an FDA pre-approval study, then the patient should not be entered into INTERMACS even if he/she receives an approved device as part of the study.

Device Type: Select from the drop down list given

- LVAD
- RVAD
- Both (in same OR visit)
- Total Artificial Heart (TAH)

Device Brand: Select from the lists provided dependent upon the selection made under Device Type above. Please refer to Appendix K (Device Brand Table from the reminder list at the bottom of this screen. Please review this document carefully as you enter devices into INTERMACS.

LVAD ▼

- Durable Devices* ▼
(Include in INTERMACS)
- HeartMate IP
 - HeartMate VE
 - HeartMate XVE
 - MicroMed DeBakey VAD – Child
 - Novacor PC
 - Novacor PCq
 - Thoratec IVAD
 - Thoratec PVAD
- Temporary Devices*
(Include only in conjunction with a durable device)
- Abiomed AB5000
 - Abiomed BVS 5000
 - Levitronix Centrimag
 - TandemHeart

RVAD ▼

- Durable Devices* ▼
(Include in INTERMACS)
- Thoratec IVAD
 - Thoratec PVAD
- Temporary Devices*
(Include only in conjunction with a durable device)
- Abiomed AB5000
 - Abiomed BVS 5000
 - Biomedicus
 - Levitronix Centrimag
 - TandemHeart

TAH ▼

Durable Devices
(Include in INTERMACS)
AbioCor TAH
SynCardia CardioWest

Implant date: enter implant date in the format mm/dd/yyyy

submit

Reminders:

1. Obtain consent pre-implant. If this is not possible, then obtain consent immediately post-implant.
2. Refer to Appendix K of the Protocol for the current list of devices and their FDA approval status.
3. Please remember to complete and submit any device tracking forms that accompany the implanted devices.

Once you have successfully completed the INTERMACS Eligibility form you will automatically be directed to the patient demographic form, the pre-implant form and the implant form. The completion of these forms will allow the user to access other forms offered in INTERMACS.

As forms are submitted, a **Patient Overview** screen is generated which lists each form and its submission status:

INTERMACS Sample Patient:

hide patient header [return to search](#) [return to home](#)

Test Patient # 999
 Institution: UAB - Test SSN (last 5 digits): 93290 DOB: 1/1/1960
 Device: RVAD Implanted 3/1/2006 Medical record number: 12098 Gender: Female

patient overview

Event	Event Date	Submission Status	Last Saved
Demographics	05/04/2006	complete	05/04/2006
Pre-Implant Quality of Life - Unknown Trail Making - Not attempted	01/01/2006	complete	05/04/2006
Implant	03/01/2006	complete	05/04/2006
Blood and Tissue Implant		complete	05/04/2006
1 Week Follow-Up	03/08/2006	complete	06/08/2006
1 Month Follow-Up	04/01/2006	complete	06/08/2006
Implant Discharge	04/10/2006	complete	05/04/2006
RVAD explantation	04/15/2006	complete	05/04/2006
AE Device Malfunction	04/15/2006		
Explant			
Explant Date	04/15/2006		
Rehospitalization			
Admission Date	04/15/2006		
Discharge Date	05/04/2006		

Done Internet

Each data element in a form must be addressed. There is a status bar (ST=) on most questions where “Unknown”, “Not Done”, or “Not Applicable” may be entered when information is just not available. Limited usage of this bar is expected. Also, many data elements have range checks. If values are entered that are outside these ranges, a “pop-up” message will advise the User.

5.6 Editing an existing patient

To add information to an existing patient, click on **Edit a patient**. This takes the User to the search facility of INTERMACS. The User may search by first name, last name, medical record number, last 5 digits of Social Security number, date of birth, device type, device brand, or implant date.

When the appropriate patient is selected, the User will be directed to the **Patient Overview** screen (as seen in the previous section). This is the primary tool for managing the data for a particular patient. This screen contains a chronological list of all existing forms for a patient. Each of these forms is accessible for viewing and editing by double-clicking on the form name. The **Patient Overview** screen gives a quick overview of the time course for a patient. The User will be able to view the status of each form, and it can serve as a reminder as to which events (forms) have been submitted. It may also serve as a condensed “medical record” that highlights the major events in an implanted patient.

5.7 Follow up

Post-implant follow up forms will be completed at 1 week, 1 month, 3 months, 6 months, and every 6 months thereafter. In general, LVAD implantation date will be the “driving force” of the follow up clock.

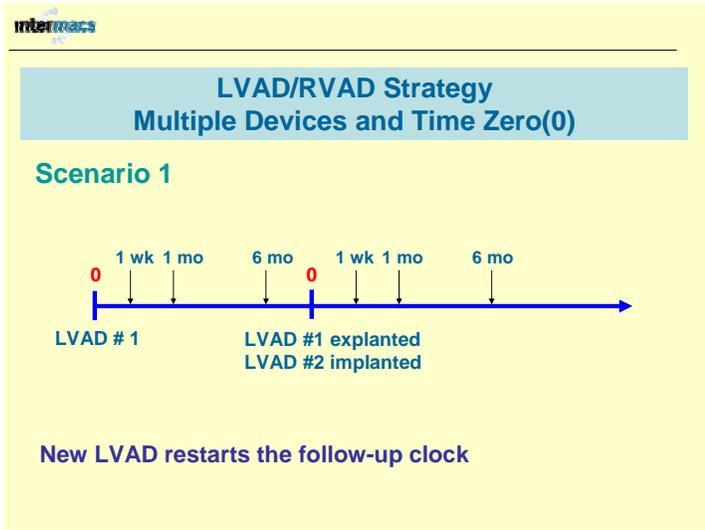
For example:

Scenario 1 – if a patient receives an LVAD, and subsequently receives another LVAD, then the follow up date is based on the implantation date of the second LVAD (see below).

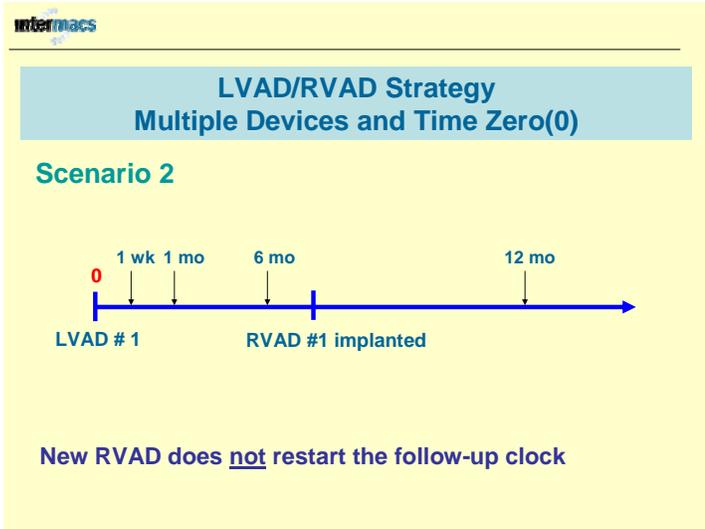
If the first implant is January 1st, the normal course of follow up would be:

January 8th - 1 week
February 1st - 1 month
April 1st - 3 months
July 1st - 6 months
and every six months thereafter.

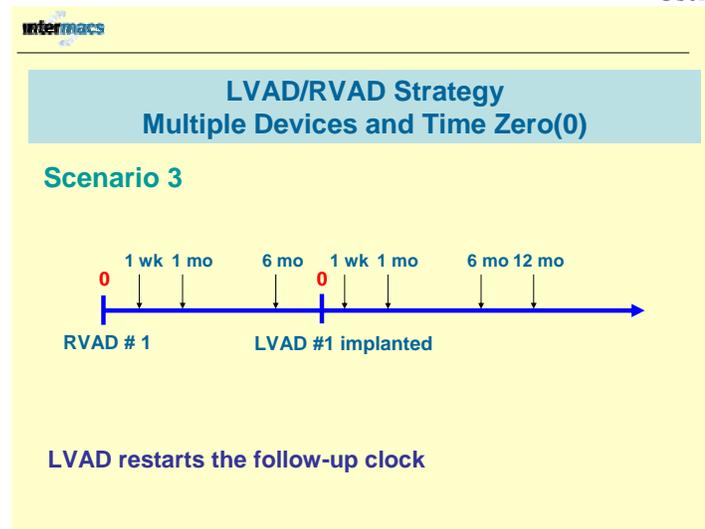
But if this patient's LVAD is exchanged on, say May 15th, then there would **not** be a six month follow up on this patient on July 1st, but rather a **new** 1 week post implant follow up on May 22nd, a new 1 month on June 15th, a new 3 month on August 15th and so forth.



Scenario 2 – if a patient receives an LVAD, and then a subsequent RVAD, then the follow up date stays based on the implantation date of the LVAD (see below). The course of follow up course does not change.



Scenario 3 – if a patient receives an RVAD first, then a subsequent LVAD, the follow up date changes and is based on the implantation date of the **new** LVAD (see below).



5.8 Adding an Event

To add an event, the User must first access the needed patient from the Edit a Patient search facility. From the **Patient Overview** screen, click the **Start here** button underneath the patient's basic demographic bar (see →).

intermacs

patient overview demographics pre implant implant

HOME MY PROFILE

hide patient header return to search return to home

Test RVAD
Institution: UAB - Test
Device: RVAD Implanted 5/5/2006

SSN (last 5 digits): 11111
Medical record number: 11111

DOB: 6/6/2000
Gender: Male

Would you like to report an event? [Start here](#)

patient overview

Event	Event Date	Submission Status	Last Saved
Demographics	05/05/2006	complete	05/05/2006
Pre-Implant Quality of Life Treat Making		complete	05/05/2006
Implant	05/05/2006	complete	05/05/2006
Blood and Tissue Implant		complete	05/05/2006
Implant Discharge		incomplete	

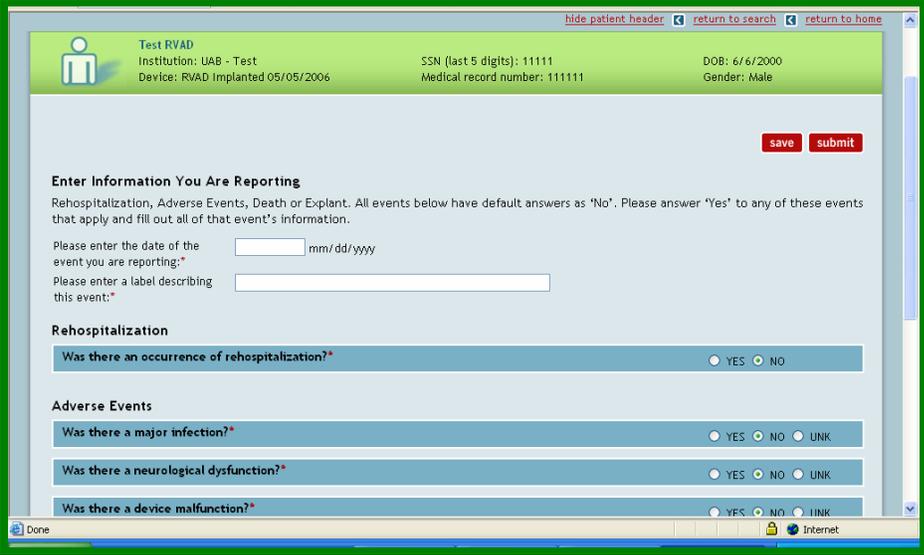
Done Internet

The User will be directed through an event report screen that contains the following information:

- Date of the event
- Label describing the event
- Event Category selections

For example, if the event category was 'Major Infection' then the User would select 'Yes' for 'Was there a major infection' under the Adverse Event heading on the event report

screen. An expanded **AE Infection** form would appear that the User may complete. The example below does not show all of the Event Category selections.



The screenshot shows a web-based form for reporting an event. At the top, patient information is displayed: Test RVAD, Institution: UAB - Test, Device: RVAD Implanted 05/05/2006, SSN (last 5 digits): 11111, Medical record number: 111111, DOB: 6/6/2000, and Gender: Male. There are 'save' and 'submit' buttons. The main section is titled 'Enter Information You Are Reporting' and includes instructions: 'Rehospitalization, Adverse Events, Death or Explant. All events below have default answers as 'No'. Please answer 'Yes' to any of these events that apply and fill out all of that event's information.' Below this are input fields for the date of the event (mm/dd/yyyy) and a label describing the event. The form then lists three categories with radio button options: 'Rehospitalization' (Was there an occurrence of rehospitalization?*), 'Adverse Events' (Was there a major infection?*, Was there a neurological dysfunction?*, Was there a device malfunction?*), and 'Adverse Events' (Was there a major infection?*, Was there a neurological dysfunction?*, Was there a device malfunction?*).

Once the User completes the event **report**, the entered events will appear as entries on the **Patient Overview** screen under the date and label entered. The events can be accessed for review and editing if needed.

5.8.1 Adding a Device

INTERMACS currently allows for entry of multiple devices for an individual patient. However, this ability is limited in that the most recent device for a patient must be removed and all forms related to the implant must be completed and validated. Additionally, the patient must be alive in order to add a new device. Once all requirements have been satisfied, the "Add Device" icon is available for the entry of a new device for the patient.



If "OK" is selected, the framework for the new device data entry will begin with a new Pre-Implant form.

The same patient demographic data will be shared between the original implant and any subsequent implants associated with the selected patient. The sample patient below has an LVAD in place and the mechanism to begin data entry for a new RVAD. Since the sample patient has a device in place and has started the process for another, the ability to enter any new devices is no longer possible and as a result the icon is no longer available.

LVAD and RVAD entries for a patient will be accessible via the links included within the "Search for an Existing Patient" page. The access format is indicated below.

Sample Patient	UNOS Test	932032-	34890	08/01/2006	LVAD	Type Unspecified	Alive
Sample Patient	UNOS Test	932032-	34890	08/20/2006	RVAD	Impella	Alive - Explant

Entering Multiple Devices of Same Type

If you wish to enter a second LVAD or RVAD for a particular patient, the first device of the same type must be removed and all forms must be validated with the exception of the Implant Discharge form. This will ensure completeness of data for the first or most recent device of the same type.

Implants within 24 hour period

Separate implants performed within any other time frame will continue to be treated as separate implant events and will not share data or be treated as a "BOTH" device. Only devices implanted within one operative procedure will be treated as a "BOTH" device.

Implant of "BOTH" Device

You may enter a single new device for the specified patient following a single device removal if the device type previously entered had been 'Both – (in the same OR visit)'. For example, if an LVAD has been removed, then the "Add Device" icon would be available and a new LVAD could be entered in parallel with the existing RVAD.

5.9 Ending Patient Participation

A patient's participation in the registry ends:

- (1) at death – complete **Death** form and relevant **AE forms** if applicable.
- (2) at transplant – complete **Transplant** form. Patient will be followed through the OPTN database.
- (3) 1 year after removal of a device due to recovery. When a patient is weaned from a device, regular follow-up form completion ceases, but the coordinator reports to the registry whether the patient died or was transplanted for a period of 1 year post-explant.

6.0 Data Dictionary

6.1 Demographics Form

The patient **Demographics Form** is to be completed upon decision of implant or as close to implant as possible and consent has been obtained. The entries with a red asterisk * are required pieces of information. These entries must be filled in.

Firstname: Enter the implant patient's first name.

MI (Middle Initial): Enter the implant patient's middle initial.

Lastname: Enter the implant patient's last name.

Medical record #: Enter the patient's hospital chart number. (The medical record number entry is optional)

SSN: Enter the implant patient's last 5-digits of their social security if in the US. If the social security number is not available, enter the last 5-digits of their UNOS waitlist ID if on the UNOS transplant wait list. If the social security number or a UNOS waitlist ID are not available, enter 12345.

Date of birth: Enter the implant patient's date of birth in MMDDYYYY format.

Gender: Click in the appropriate circle to indicate the implant patient's gender.

Ethnicity: **Hispanic or Latino:** Select Yes or No

Race: Enter all race choices that apply from the list below:

- American Indian or Alaska Native
- Asian
- African-American or Black
- Hawaiian or Other Pacific Islander
- White
- Unknown/Undisclosed
- Other/none of the above

Marital status: Enter patient's current marital status from the list below:

- Single
- Married
- Divorced/Separated
- Widowed
- Unknown

Highest education level: Enter patient's current highest education level from the list below:

- None
- Grade School (0-8)
- High School (9-12)
- Attended College/Technical School
- Associate/Bachelor Degree
- Post-College Graduate Degree
- N/A (< 5 yrs old)
- Unknown

Working for income: Answer this question if patient is over 18 years of age. Select **Yes** if the patient is currently working for income or attending school. If not, select **No**. If unknown, select **Unknown**.

If **Yes**, select one of the following:

- Working Full Time
- Working Part Time due to Demands of Treatment
- Working Part Time due to Disability
- Working Part Time due to Insurance Conflict
- Working Part Time due to Inability to Find Full Time Work
- Working Part Time due to Patient Choice
- Working Part Time Reason Unknown
- Working, Part Time vs. Full Time Unknown

If **No**, select reason patient is not working from one of the following:

- Disability
- Demands of Treatment
- Insurance Conflict
- Inability to Find Work
- Patient Choice - Homemaker
- Patient Choice - Student Full Time/Part Time
- Patient Choice - Retired
- Patient Choice - Other
- Not Applicable - Hospitalized
- Unknown

Academic Progress: If patient is less than or equal to 18 years of age, enter one of the selections below:

- Within One Grade Level of Peers
- Delayed Grade Level
- Special Education
- Not Applicable < 5 years old
- Status Unknown

Academic Activity Level: If patient is less than or equal to 18 years of age, enter one of the selections below:

Full Academic Load
 Reduced Academic Load
 Unable to participate in academics due to disease or condition
 Not Applicable < 5 years old/High School graduate
 Status Unknown

6.2 Pre-Implant Form

The Pre-implant Form Date of Collection should be the date closest prior to the VAD implant date but not more than 1 month prior to VAD implant decision date. (The VAD implant decision date is the date on which the patient (or family) agrees to the VAD team's recommendation for a VAD implant. If there are implant decision date discrepancies recorded in the patient's records, use the earliest one as the decision date.)

Pediatric/congenital – collect this variable for VAD patients less than 19 years of age or primary diagnosis is congenital. ***Except for Ross Classification under the Medical Condition Section, this information is collected only for patients < 6 years of age.***

DEMOGRAPHICS

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. ST(status)=Unknown

Weight: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. ST(status)=Unknown

Blood Type: Select the patient's blood type.

MEDICAL SUPPORT STATUS

Current Device Strategy: This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant decision. This determination will be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter. The strategy should be selected as:

Bridge to recovery

Bridge to transplant– this is for a patient ALREADY listed for transplant or listed within 24 hours before device implantation

Possible bridge to transplant - *Likely to be eligible:* defines a patient in whom the transplant evaluation has not been completed but no contra-indications are

anticipated, or in whom a current contra-indication is anticipated to resolve rapidly, such as recent infection

Possible bridge to transplant -Moderate likelihood of becoming eligible: similar to above, but with some potential concerns that might prevent eligibility.

Possible bridge to transplant -Unlikely to become eligible: should be used for a patient in whom major concerns have already been identified. These may not yet have been quantified, such as in a patient with known chronic lung disease without recent pulmonary function test measurement, or might be reversible, such as severe renal insufficiency or pulmonary hypertension that might improve after chronic mechanical support. It may be the expectation at the time of implant that the patient will most likely have the assist device as “permanent” or “destination” therapy.

Destination therapy (patient definitely not eligible for transplant). All factors that weigh in to the decision of non –transplant candidacy should be indicated below.

Other, specify type in the specification in the block provided.

Current Device Strategy:

Transplant Eligibility Issues or Contraindications to Transplant:

If you select Possible Bridge to Transplant or Destination Therapy, then check all that apply.

Checking these does not necessarily mean that a condition is a contra-indication.

There are often many reasons why a patient is not an ideal candidate for transplantation, although it may still represent the best option for the patient. No specific thresholds are provided for these concerns or contra-indications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation. If there are no contraindications specified then select None.

Implant decision date: This is the date the decision was made to implant the device, not necessarily the date of implantation.

Time since first cardiac diagnosis: the length of time that the patient had any known cardiac diagnosis. For example: time since the patient had a myocardial infarction, congenital heart disease was noted or the patient was noted to have heart failure. (see drop down)

Cardiac diagnosis/primary: **Check one** primary reason for cardiac dysfunction (see drop down).

Cardiac diagnosis/secondary: **Check all that apply** for secondary cardiac diagnoses. For example, a patient might have dilated myopathy: idiopathic as a first primary diagnosis and may have superimposed mitral regurgitation and thus have valvular heart disease.

Cardiac Diagnosis, Congenital: If primary cardiac diagnosis is congenital, then check all that apply from the type of congenital heart disease listed. If **Other specify** is selected, type in the specification in the block provided.

Known Cardiac biopsy: If the patient has had an endomyocardial or direct myocardial biopsy, select from the diagnoses listed in the drop down. If the patient has had more than one biopsy, the one closest to implantation date should be listed. If no biopsy is known, select "no biopsy known". If **Other specify** is selected, type in the specification in the block provided.

Previous cardiac operation: Check all cardiac operations that the patient has had prior to MCS D implantation. If **Other specify** is selected, type in the specification in the block provided.

Congenital surgeries: If congenital cardiac surgery, check all surgeries that apply in the list provided. If **Other specify** is selected, type in the specification in the block provided. If **Previous mechanical support, specify** is selected, list any eligible MCS D support prior to the current implantation MCS D, or any other mechanical device support previous to the current MCS D.

Reason for Admission: Select one primary reason the patient was admitted for the index hospitalization during which the decision to implant an MCS D was made.

Current ICD device in place: If the patient currently has an implantable defibrillator, then "yes" should be checked. If the patient has already had it explanted at the time of the MCS D implant, then "no" should be checked. Note that patients with bi-ventricular pacing and ICD should have "Yes" checked for ICD also.

Events this hospitalization (Pre-implant): Pertaining to the index hospitalization, select all other events that apply.

If event this hospitalization is Major Infection, Select infection type: Select one infection type of the event that happened during the index hospitalization.

If event this hospitalization is Major Infection, Select location of infection: Select the location of the infection that occurred during the index hospitalization. If **Other specify** is selected, type in the specification in the block provided.

IV inotrope therapy at implant: If the patient has gone to the operating room for the purpose of the implant and is on intravenous inotropes of any sort, the answer should be "yes". If an agent is known to have been used but discontinued within 4 hours prior to arriving in the operating room, "Yes" should also be checked.

If yes, IV inotrope therapy agents: Check all intravenous inotropes used at the time of the MCS D implant that apply. If **Other specify** is selected, type in the specification in the block provided.

Additional support interventions within 24 hours of implant: Check all other therapies necessary within the 24 hours prior to MCS D implant that apply.

Additional support interventions within 24 hours of implant – ECMO may be selected if patient is less than 19 years of age.

Patient profile/status: Select one. These statuses will provide better description of the patients receiving implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, the status closest to the time of implant should be recorded. **A-modifier** - Recurrent ventricular tachyarrhythmias may dominate the clinical picture. An A modifier should be added to the level for ventricular tachycardia or fibrillation with repeated shocks from ICD or external defibrillator, usually more than 2 weekly. The A-modifier may be added to any INTERMACS level except Level 7, (e.g. Level 4-A).

INTERMACS 1: Critical cardiogenic shock describes the patient who is “crashing and burning”, in which patients have life-threatening hypotension despite rapidly escalating inotropic pressor support, occasionally with IABP placement as well, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels.

INTERMACS 2: Progressive decline describes the patient who has been demonstrated “dependent” on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Level 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmias, clinical ischemia, or other intolerance.

INTERMACS 3: Stable but inotrope dependent describes clinical stability on mild-moderate doses of intravenous inotropes after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between patients who are truly stable at Level 3 and those who have unappreciated decline rendering them Level 2.

INTERMACS 4: is the level of “recurrent” rather than “refractory” decompensation. After interventions such as hospitalization for intravenous diuretics, these patients can be stabilized briefly on an oral regimen at close to normal volume status. However, they experience brief relapses into fluid retention. These patients should be carefully considered for more intensive management and surveillance programs, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy.

INTERMACS 5: describes patients who are comfortable at rest but are exercise intolerant for most activity, living predominantly within the house or housebound. They have no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as housebound.

INTERMACS 6: is a similar patient who is generally without any evidence of fluid overload and able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or

going to a restaurant can be performed, but fatigue results within a few minutes or any meaningful physical exertion.

INTERMACS 7: describes patients who are clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. Any decompensation requiring intravenous diuretics or hospitalization within the previous 2 weeks should make the person a Level 4 or lower.

CO-MORBIDITIES

Diabetes: Indicate if the patient has a history of diabetes at the time of the hospitalization for the MCS D implant.

If yes Diabetes insulin dependent: Referring to the index hospitalization during which the MCS D was implanted.

Cardiac rhythm: Select one predominant rhythm of the patient during the index hospitalization for the MCS D implantation. If **Other specify** is selected, type in the specification in the block provided.

COPD: The history of known **chronic obstructive pulmonary disease** at the time of device implantation **and** whether there is specific treatment being administered for COPD.

Symptomatic Peripheral vascular disease: At the time of the index hospitalization, is the patient complaining of either claudication or other manifestations of peripheral vascular disease? If so, check yes. Known and documented peripheral vascular disease in the absence of symptoms should be checked as “yes” as well.

Connective tissue or inflammatory rheumatologic disease: A known diagnosis of either at the time of index hospitalization. Yes, No, or Unknown.

Hx of hepatitis A: History of symptoms or serologic evidence of the disease pertinent to index hospitalization. Yes, No, or Unknown.

Hx of Hepatitis B: History of symptoms or serologic evidence of the disease pertinent to index hospitalization. Yes, No, or Unknown.

Hx of Hepatitis C: History of symptoms or serologic evidence of the disease pertinent to index hospitalization. Yes, No, or Unknown.

Peripheral Myopathy: Skeletal muscle biopsy abnormality of skeletal muscle or weakness by physical examination. Yes, No, or Unknown.

Protein Losing Entropathy: Elevated alpha-1 anti-trypsin or I.V. albumin replacement for greater than 14 days. Yes, No, or Unknown.

If yes, check all evidence that apply:

Elevated Aphas 1 antitrysin

Albumin IV requirement

Clinical diagnosis

Unknown

Carotid artery disease: Having signs or symptoms of carotid artery disease or greater than 50% narrowing of carotid. Yes, No, or Unknown.

History of Neurological Event: Select **CVA** (cerebro-vascular accident), **TIA** (transient ischemic attack), or **unknown** for the patient at the time of the index hospitalization.

Cancer other than local skin cancer: Yes, No, or Unknown pertaining to the history of cancer at the time of the index hospitalization. Note that local skin cancers are excluded.

If yes, Type of cancer: Select all that apply from drop down list. If **Other specify** is selected, type in the specification in the block provided.

Any active treatment for cancer at time of implant (other than local skin cancer):

Has treatment for cancer been administered for a cancer during the index hospitalization? Yes, No, and Unknown.

Smoking History: Select one of the following pertaining to the patient's history of smoking tobacco:

Currently

Within the past 3 months

More than 3 months ago

Never

Unknown

If smoking history exists, then: enter the number of pack years or unknown. **Pack Years** - The number of packs of cigarettes the candidate smoked per day multiplied by the number of years. For example a candidate smoking 2 packs of cigarettes per day for 10 years would equal 20 pack years.

History of previous alcohol abuse: Yes, No, or Unknown based on the patient's self-acknowledgment of alcohol abuse.

If alcohol abuse history exists, then: select current alcohol use from among these choices:

None

Modest

Heavy

None, but no known abuse within past year
Unknown

Drug abuse: Select one of the following pertaining to the patient's self-acknowledged abuse of illicit or prescription drugs:

Currently
Within the past 3 months
More than 3 months ago
Never
Unknown

Cardiac research trial device: Yes, No, or Unknown. If the patient is having a device **other than an MCSD** implanted and this device is not yet FDA approved for therapy, the name of the device should be typed in the block provided.

Cardiac research trial drug: Yes, No, or Unknown. If the patient is currently receiving a drug that is not FDA approved, the name of the drug should be typed in the block provided.

Transfusion history: Yes, No, or Unknown. At the time of implantation, has the patient ever been transfused with blood in their lifetime?

HEMODYNAMICS (Prior to implant)

General Hemodynamics

Heart rate: beats per minute. ST= unknown or not done.

Systolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Diastolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Volume status (peripheral edema): Volume status is determined from peripheral edema and ascites. Select one from none, mild, moderate, severe, unknown and not done. This would equate to 0, 1+, 2+ and 3-4+ would be severe.

Ascites: Yes, No or Unknown. This is in the clinicians' best guess, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

ECG rhythm (cardiac rhythm): Select one of the following. If **Other specify** is selected, type in the specification in the block provided.

Sinus
Atrial fibrillation
Atrial flutter
Paced

Not done
Other, specify
Unknown

Echo Hemodynamics

Were Echo Hemodynamics performed pre-implant? Yes, No or Unknown. If yes, continue through each type:

LVSF: left ventricular shortening fraction is a measure of contractility instead of ejection fraction, used largely in pediatrics. This does NOT need to be recorded if a left ventricular ejection fraction (LVEF) is available (to be recorded below). ST= unknown and not done.

Mitral regurgitation: mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild):

- 0 (none)**
- 1 (mild)**
- 2 (moderate)**
- 3 (severe)**
- ST= unknown and not done.**

Tricuspid regurgitation: tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild):

- 0 (none)**
- 1 (mild)**
- 2 (moderate)**
- 3 (severe)**
- ST= unknown and not done.**

Aortic regurgitation: aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild):

- 0 (none)**
- 1 (mild)**
- 2 (moderate)**
- 3 (severe)**
- ST= unknown and not done.**

LVEF% Left ventricular ejection fraction. If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, moderate-severe would be recorded as "severe".

- > 50 (normal)
- 40 -50 (mild)
- 30-40 (moderate)
- 20-30 (moderate/severe)

< 20 (severe)
Not done
Unknown

LVEDD: left ventricular end-diastolic dimension in centimeters.

RVEF: is generally NOT measured in numbers, as it is difficult to quantify. It may be described as “right ventricular function” or “right ventricular contractility”. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Swan Hemodynamics

Was a swan in place before implant? Yes, No or Unknown. If yes, continue through each measurement:

Shunt ratio (QpQs): this number will rarely be calculated except in the pediatric population. Do not look for it unless it is clearly provided. ST= Unknown and Not done.

Pulmonary artery systolic pressure: This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

Pulmonary artery diastolic pressure: This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

RA Pressure: May be listed also as RAP or CVP. ST= Unknown and Not done.

Pulmonary artery wedge pressure: May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. ST= Unknown and Not done.

Cardiac output: will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m² or L/min/m². ST= Unknown and Not done.

MEDICATIONS collected at time of decision for implant. Mark whether the medications listed fall into one of the following categories:

Currently using - at the time of decision for VAD placement, even if this precedes VAD placement for days.

Known previous use within the past year- is intended to capture the adequacy of medical therapy prior to determining heart failure to be refractory. For instance, ACEI, beta blockers, and diuretics are considered standard necessary therapy for heart failure but may be stopped due to hypotension or renal failure during a hospitalization for severely decompensated heart failure. If patients are known to have received these agents within the past year, please check "known previous use".

No (not being used) - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check NO.

Unknown - If it is not known whether the patient has taken those agents within the previous year, check "unknown".

List of medications

Angiotension receptor blocker drug

Amiodarone

ACE inhibitors

Beta-blockers

Aldosterone antagonist

Loop diuretics

Warfarin (coumadin)

Anteplatelet therapy drug

Nesiritide Check YES for **Nesiritide** only if currently being administered. Note that there is no option for previously taken.

Nitric oxide Check YES for **nitric oxide** only if currently being administered. Note that there is no option for previously taken.

Outpatient (prior to admission) inotrope infusion: check all that apply.

LABORATORY VALUES collected nearest to time of implant

The laboratory values are the LAST values available prior to implant. (Note that this is different from the medications, which are taken closest to the time of MCSD decision.) It is anticipated that the blood urea nitrogen, creatinine, total bilirubin, sodium, INR, white blood cell count, platelet count, and SGOT and SGPT will usually be measured within 48 hours of the implant surgery. Other lab values may be less recent. Values obtained more than a month prior to the implant date should not be included. For all of the tests listed below, give the appropriate measurement or check unknown or not done:

Blood urea nitrogen

Creatinine

Total bilirubin

Sodium

INR

White blood cell count

Platelet

SGOT/AST (aspartate aminotransferase/AST)

SGPT/ALT (alanine aminotransferase/ALT)

Cholesterol
CRP (C Reactive Protein)
Potassium
Hemoglobin
Protein C
Protein S
Anti-phospholipid (IgG)
Pre-albumin
Albumin

Institutions generally perform only one of the two following assays. The other one should be indicated as "not done".

Brain natriuretic peptide BNP
NT pro brain natriuretic peptide Pro-BNP

MEDICAL CONDITION

NYHA Class (patient \geq 6 yrs of age): New York Heart Association Class for heart failure:

For patients greater than or equal to 6 years of age.

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea

Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitations, or dyspnea.

Class III: Marked limitation of physical activity. Comfortable at rest but modest exertion causes fatigue, palpitations, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency may be present at rest or with any minimal exertion, such as walking between rooms. If any physical activity is undertaken, discomfort is increased.

Unknown

Ross Classification of Congestive Heart Failure (patient $<$ 6 yrs of age):

If Ross Class I: no limitations or symptoms.

If Ross Class II: no growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class III: growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class IV: symptomatic at rest. If selected, choose all indicated symptoms that apply.

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps:

Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest).

A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, check all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear.

If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists.

If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select unknown.

EXERCISE FUNCTION

6 minute walk: This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.

VO2 Max: Maximum volume of oxygen the body can consume during exercise (mL/min)

is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize. Too sick, not done, and other, specify.

R Value at peak:

is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

Quality of Life (EUROqoL)

Please see the EUROqoL section of the Data Dictionary for further instructions on the EUROqoL web-based data entry. A missing data form is completed when the EuroQoL/Trail Making Test were not complete within specified window of time for followup (ie., pre-implant, 3 month followup or q 6 month followup). Please see the Missing EuroQoL/Trail Making Test Data Form.

Neurocognitive Trail Making Test – Part B

Please see the Trail Making Test Part B Instructions section of the Data Dictionary for further instructions on administration and web-based data entry for the Trail Making Test. A missing data form is completed when the EuroQoL/Trail Making Test were not complete within specified window of time for followup (ie., pre-implant, 3 month followup or q 6 month followup). Please see the Missing EuroQoL/Trail Making Test Data Form.

6.3 Implant

The **Implant Form** is to be completed within 1 week of the Implant.

Additional Indication for VAD: Select one of the following as indication for VAD.

Failure to wean from CPB:
Post cardiac surgery
None

If post cardiac surgery, **Enter Cardiac operation:** Type the cardiac operation performed

Implant date: enter VAD implant date in mmddyyyy format.

Device Type: select one of the following as VAD device type implanted.

LVAD
RVAD
Both (in the same OR visit)
Total Artificial Heart (TAH)

Brand of device: select the device brand from the list provided. If **Other specify** is selected, type in the specification in the block provided. This list is available for LVAD, RVAD, BOTH (if LVAD/RVAD implanted in the same OR visit) and TAH (total artificial heart). Please refer to Appendix K (Brand Device Table) if you have questions or are unsure as to what devices should and should not be included into INTERMACS. Appendix K is available on www.intermacs.org at "All Things INTERMACS" under Manuals. Please review this document carefully.

LVAD	RVAD	TAH
<i>Durable Devices</i> (Include in INTERMACS)	<i>Durable Devices</i> (Include in INTERMACS)	<i>Durable Devices</i> (Include in INTERMACS)
HeartMate IP	Thoratec IVAD	AbioCor TAH
HeartMate VE	Thoratec PVAD	
SynCardia CardioWest		
HeartMate XVE	<i>Temporary Devices</i>	
MicroMed DeBakey VAD–Child	(Include only in conjunction with a durable device)	
Novacor PC	Abiomed AB5000	
Novacor PCq	Abiomed BVS 5000	
Thoratec IVAD	Biomedicus	
Thoratec PVAD	Levitronix Centrimag	
<i>Temporary Devices</i> (Include only in conjunction with a durable device)	TandemHeart	
Abiomed AB5000		
Abiomed BVS 5000		
Levitronix Centrimag		
TandemHeart		

device tracking number: enter unique serial number for each device.

console tracking number: enter unique serial number for console for each device (LVAD/RVAD) at time of implant.

LVAD: cannulae location-inflow: select one of the following for LVAD cannulae inflow location.

LA appendage
LA interatrial groove
LV apex
Unknown

LVAD: cannulae location-outflow: select one of the following for LVAD cannulae inflow location.

Ascending aorta
Descending thoracic aorta
Abdominal aorta
Unknown

If RVAD Berlin Heart: What is the Pump Volume of the artificial ventricle?:

RVAD: cannulae location-inflow: Location of inflow cannulae:

RA,
RV,
Unknown

Concomitant surgery: check all concomitant surgeries that apply. If **Other** specify is selected, type in the specification in the block provided.

None	Valve Surgery: Aortic Replacement - Biological
ASD closure	Valve Surgery: Mitral Replacement - Mechanical
PFO closure	Valve Surgery: Mitral Replacement - Biological
RVAD implant	Valve Surgery: Tricuspid Replacement -
Mechanical	
ECMO decannulation	Valve Surgery: Tricuspid Replacement -
Biological	
CABG	Valve Surgery: Pulmonary Replacement -
Mechanical	
VSD closure	Valve Surgery: Pulmonary Replacement - Biological
Congenital cardiac surgery	Other, specify
Valve Surgery: Aortic Repair	
Valve Surgery: Mitral Repair	
Valve Surgery: Tricuspid Repair	
Valve Surgery: Pulmonary Repair	
Valve Surgery: Aortic Replacement - Mechanical	

CPB time: (Total cardiopulmonary bypass time): enter total cardiopulmonary bypass time in minutes. ST= Unknown or Not done.

Time in OR for implant: enter time in Operating Room for implant in minutes.
ST=Unknown

6.4 1 week and 1 month post implant information

The data on this form is collected at 1 week (+/- 2 days) post-implant and 1 month (+/- 7 days) post implant if the patient is still hospitalized with a VAD in place (i.e., not transplanted) during the implant hospitalization. (When you perform medical chart abstraction, please use the hospital day closest to 1 week (+/- 7 days) post-implant.) If the patient is no longer hospitalized, with a VAD in place, at 1 week or 1 month post-implant, the 1 week and 1 month post implant information form should not be completed. (Please check "No" on the 1 week and/or 1 month post implant information form if the patient is no longer hospitalized with a VAD in place at 1 week or 1 month status post VAD implant.)

Pediatric/congenital – collect this variable for VAD patients less than 19 years of age or primary diagnosis is congenital. ***Except for Ross Classification under the Medical Condition Section, this information is collected only for patients < 6 years of age.***

Is patient still in hospital at 1 week (+/- 2 days) from implant surgery? Yes, No and Unknown

-Or -

Is patient still in hospital at 1 month (+/- 7 days) from implant surgery? Yes, No and Unknown

Post implant date: enter date post-implant in mmddyyyy format.

HEMODYNAMICS

General Hemodynamics

Heart rate: beats per minute. ST= unknown or not done.

Systolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Diastolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Volume status (peripheral edema): Volume status is determined from peripheral edema and ascites. Select one from none, mild, moderate, severe, unknown and not done. This would equate to 0, 1+, 2+ and 3-4+ would be severe.

Ascites: Yes, No or Unknown. This is in the clinicians' best guess, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

ECG rhythm (cardiac rhythm): Select one of the following. If **Other specify** is selected, type in the specification in the block provided.

Sinus
Atrial fibrillation
Atrial flutter
Paced
Not done
Other, specify
Unknown

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. ST= Unknown or Not Done

Weight: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. ST= Unknown or Not Done

Echo Hemodynamics

Were Echo Hemodynamics performed at 1 week/1 month? Yes, No or Unknown. If yes, continue through each measurement:

LVSF: left ventricular shortening fraction is a measure of contractility instead of ejection fraction, used largely in pediatrics. This does NOT need to be recorded if a left ventricular ejection fraction (LVEF) is available (to be recorded below). ST= unknown and not done.

Mitral regurgitation: mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

0 (none)
1 (mild)
2 (moderate)
3 (severe)
ST= unknown and not done.

Tricuspid regurgitation: tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

0 (none)
1 (mild)
2 (moderate)
3 (severe)
ST= unknown and not done.

Aortic regurgitation: aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

0 (none)
1 (mild)

2 (moderate)

3 (severe)

ST= unknown and not done.

LVEF% Left ventricular ejection fraction. If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as “left ventricular function” or “systolic function” in words. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, moderate-severe would be recorded as “severe”.

> 50 (normal)

40 -50 (mild)

30-40 (moderate)

20-30 (moderate/severe)

< 20 (severe)

Not Done

Unknown

LVEDD: left ventricular end-diastolic dimension in centimeters.

RVEF: is generally NOT measured in numbers, as it is difficult to quantify. It may be described as “right ventricular function” or “right ventricular contractility”. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Swan Hemodynamics

Is a swan in place at 1 week/1 month? Yes, No or Unknown. If yes, continue through each measurement:

Shunt ratio (QpQs): this number will rarely be calculated except in the pediatric population. Do not look for it unless it is clearly provided. ST= Unknown and Not done.

Pulmonary artery systolic pressure: This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

Pulmonary artery diastolic pressure: This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

RA Pressure: May be listed also as RAP or CVP. ST= Unknown and Not done.

Pulmonary artery wedge pressure: May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. ST= Unknown and Not done.

Cardiac output: will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m² or L/min/m². ST= Unknown and Not done.

MEDICATIONS

Currently on IV inotrope therapy at 1 week/1 month? Yes, No or Unknown.

If yes, IV inotrope therapy agents: Check all intravenous inotropes used at 1 week/1 month. If **Other specify** is selected, type in the specification in the block provided.

Mark whether the medications listed are used at 1 week/1 month: Yes, No or Unknown.

List of medications

Nesiritide

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

Beta-blockers

Aldosterone antagonist

Loop diuretics

Warfarin (coumadin)

Anteplatelet therapy drug – additionally, check all that apply.

Nitric oxide

LABORATORY VALUES

Values closest to 1 week and 1 month anniversaries. For all of the tests listed below, give the appropriate measurement or check unknown or not done:

Blood urea nitrogen

Creatinine

Total bilirubin

Bilirubin direct

Bilirubin indirect

Sodium

INR

White blood cell count

Platelet

SGOT/AST (aspartate aminotransferase/AST)

SGPT/ALT (alanine aminotransferase/ALT)

Cholesterol

CRP (C Reactive Protein)

Potassium

Hemoglobin

Plasma free hemoglobin**Reticulocyte count**

Patient has positive antiheparin/platelet antibody (HIT) – Yes, No, or Unknown

If yes, are they on direct thrombin inhibitors – Yes, No, or Unknown

If yes, check all that apply (aspirin, dipyridamole, plavix,

heparin,

coumadin, direct thrombin inhibitors)

LDH

TEG profile, MA k

TEG profile, Rk

TEG profile, Rh

Protein C

Protein S

Anti-phospholipid (IgG)

Pre-albumin

Albumin

Institutions generally perform only one of the two following assays. The other one should be indicated as “not done”.

Brain natriuretic peptide BNP**NT pro brain natriuretic peptide Pro-BNP****MEDICAL CONDITION**

NYHA Class (patient \geq 6 yrs of age): New York Heart Association Class for heart failure:

For patients greater than or equal to 6 years of age.

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea

Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitations, or dyspnea.

Class III: Marked limitation of physical activity. Comfortable at rest but modest exertion causes fatigue, palpitations, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency may be present at rest or with any minimal exertion, such as walking between rooms. If any physical activity is undertaken, discomfort is increased.

Unknown

Ross Classification of Congestive Heart Failure (patient < 6 yrs of age):

If Ross Class I: no limitations or symptoms.

If Ross Class II: no growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class III: growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class IV: symptomatic at rest. If selected, choose all indicated symptoms that apply.

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps:

Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest). A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, check all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear. If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists. If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select unknown.

Please go to Section 6.16 for information about the Adverse Event Reminder section of this form.

6.5 3 month and 6 month follow up

The data on this form is collected at 3 months post-implant and every 6 months post-implant. When doing medical chart abstraction, please use clinic visit closest to 3 and 6 month anniversaries (perpetual). The clinic visit must be within 1 month of the 3 month or within 2 months for every 6 month visit.

Pediatric/congenital – collect this variable for VAD patients less than 19 years of age or primary diagnosis is congenital. ***Except for Ross Classification under the Medical Condition Section, this information is collected only for patients < 6 years of age.***

Was patient seen in the hospital or clinic at follow-up time period (+/- 1 month if 3 month followup or +/- 2 months if q 6 month followup) ? Yes, No and Unknown

Date of followup: enter date in mmdyyy format.

HEMODYNAMICS

General Hemodynamics

Heart rate: beats per minute. ST= unknown or not done.

Systolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Diastolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Volume status (peripheral edema): Volume status is determined from peripheral edema and ascites. Select one from none, mild, moderate, severe, unknown and not done. This would equate to 0, 1+, 2+ and 3-4+ would be severe.

Ascites: Yes, No or Unknown. This is in the clinicians' best guess, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

ECG rhythm (cardiac rhythm): Select one of the following. If **Other specify** is selected, type in the specification in the block provided.

Sinus
Atrial fibrillation
Atrial flutter
Paced
Not done
Other, specify
Unknown

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. ST= Unknown or Not Done

Weight: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. ST= Unknown or Not Done

Echo Hemodynamics

Were Echo Hemodynamics performed at 3 months post-implant or at a 6 month post-implant interval? Yes, No or Unknown. If yes, continue through each measurement:

LVSF: left ventricular shortening fraction is a measure of contractility instead of ejection fraction, used largely in pediatrics. This does NOT need to be recorded if a left ventricular ejection fraction (LVEF) is available (to be recorded below). ST= unknown and not done.

Mitral regurgitation: mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

0 (none)

1 (mild)

2 (moderate)

3 (severe)

ST= unknown and not done.

Tricuspid regurgitation: tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild)..

0 (none)

1 (mild)

2 (moderate)

3 (severe)

ST= unknown and not done.

Aortic regurgitation: aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild)..

0 (none)

1 (mild)

2 (moderate)

3 (severe)

ST= unknown and not done.

LVEF% Left ventricular ejection fraction. If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, moderate-severe would be recorded as "severe".

> 50 (normal)

40 -50 (mild)

30-40 (moderate)

20-30 (moderate/severe)

< 20 (severe)

Not done

Unknown

LVEDD: left ventricular end-diastolic dimension in centimeters.

RVEF: is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".

Swan Hemodynamics

Is a swan in place at 3 months/6months? Yes, No or Unknown. If yes, continue through each measurement:

Shunt ratio (QpQs): this number will rarely be calculated except in the pediatric population. Do not look for it unless it is clearly provided. ST= Unknown and Not done.

Pulmonary artery systolic pressure: This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

Pulmonary artery diastolic pressure: This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). ST= Unknown and Not done.

RA Pressure: May be listed also as RAP or CVP. ST= Unknown and Not done.

Pulmonary artery wedge pressure: May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. ST= Unknown and Not done.

Cardiac output: will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m² or L/min/m². ST= Unknown and Not done.

MEDICATIONS

Currently on IV inotrope therapy? Yes, No or Unknown.

If currently on Inotrope, list drug: Check all intravenous inotropes used at 3 months/6 months. If **Other specify** is selected, type in the specification in the block provided.

Mark whether the medications listed are used at 3 months/6 months: Yes, No or Unknown.

List of medications**Nesiritide****Angiotensin receptor blocker drug****Amiodarone****ACE inhibitors****Beta-blockers****Aldosterone antagonist****Loop diuretics****Warfarin (coumadin)****Anteplatelet therapy drug** – additionally, check all that apply.**Nitric oxide**If **Other specify** is selected, type in the specification in the block provided.**LABORATORY VALUES**

Values closest to 3 and 6 month follow-up (as specified at beginning of this form). For all of the tests listed below, give the appropriate measurement or check unknown or not done:

Blood urea nitrogen**Creatinine****Total bilirubin****Bilirubin direct****Bilirubin indirect****Sodium****INR****White blood cell count****Platelet****SGOT/AST** (aspartate aminotransferase/AST)**SGPT/ALT** (alanine aminotransferase/ALT)**Cholesterol****CRP (C Reactive Protein)****Potassium****Hemoglobin****Plasma free hemoglobin****Reticulocyte count****Patient has positive antiheparin/platelet antibody (HIT)** – Yes, No, or Unknown

If yes, are they on direct thrombin inhibitors – Yes, No, or Unknown

If yes, check all that apply (aspirin, dipyridamole, plavix, heparin, coumadin, direct thrombin inhibitors).

LDH**TEG profile, MA k****TEG profile, Rk****TEG profile, Rh****Protein C****Protein S****Anti-phospholipid (IgG)****Pre-albumin**

Albumin

Institutions generally perform only one of the two following assays. The other one should be indicated as "not done".

Brain natriuretic peptide BNP NT pro brain natriuretic peptide Pro-BNP

DEVICE PARAMETERS

LVAD Device type Select Pulsatile or Rotary

RVAD Device type Select Pulsatile or Rotary or none

Device Parameters - Pulsatile

if LVAD/RVAD/TAH device selection is pulsatile, answer the following questions:

LVAD/TAH (left side) questions:

LVAD/TAH (left side) flow : in liters per minute. ST= unknown or not done.\

LVAD/TAH (left side) - pump drive pressure (pneumatic devices only) – mmHg (millimeters of Mercury) ST= unknown or not done.

LVAD/TAH (left side) control mode: Select one of the modes from the list provided.

Auto mode (or fill-to-empty)
Fixed
Unknown

LVAD/TAH (left side) – Fixed: Enter rate. ST= unknown or not done.

RVAD/TAH (right side) questions:

RVAD/TAH (right side) flow in liters per minute. ST= unknown or not done.

RVAD/TAH (right side) - pump drive pressure (pneumatic devices only) mmHg (millimeters of Mercury) ST= unknown or not done.

RVAD/TAH (right side) control mode: Select one of the modes from the list provided.

Auto mode (or fill-to-empty)
Fixed
Unknown

RVAD/TAH (right side) – Fixed: Enter rate. ST= unknown or not done.

Device Parameters - Rotary

if LVAD/RVAD/TAH device selection is Rotary, answer the following questions

LVAD/TAH (left side) flow in liters per minute. ST= unknown or not done.

LVAD/TAH (left side) pump speed – revolutions per minute

LVAD/TAH (left side) power (watts) – enter watts

LVAD/TAH (left side) current (amps) – enter amps

RVAD/TAH (right side) flow in liters per minute. ST= unknown or not done.

RVAD/TAH (right side) pump speed - revolutions per minute

RVAD/TAH (right side) power (watts) - enter watts

RVAD/TAH (right side) current (amps) – enter amps

EXERCISE FUNCTION

6 minute walk: This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.

VO2 Max: Maximum volume of oxygen the body can consume during exercise (mL/min)

is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize. Too sick, not done, and other, specify.

R Value at peak:

is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

MEDICAL CONDITION

NYHA Class (patient \geq 6 yrs of age): New York Heart Association Class for heart failure:

For patients greater than or equal to 6 years of age.

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea

Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitations, or dyspnea.

Class III: Marked limitation of physical activity. Comfortable at rest but modest exertion causes fatigue, palpitations, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency may be present at rest or with any minimal exertion, such as walking between rooms. If any physical activity is undertaken, discomfort is increased.

Unknown

Has patient been rehospitalized since implant hospitalization?: Yes, No, or Unknown

Pediatric – collect this variable for VAD patient less **than 6 years of age**

Ross Classification of Congestive Heart Failure (patient < 6 yrs of age):

If Ross Class I: no limitations or symptoms.

If Ross Class II: no growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class III: growth failure. If selected, choose all indicated symptoms that apply.

If Ross Class IV: symptomatic at rest. If selected, choose all indicated symptoms that apply.

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps:

Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest). A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, check all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear. If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists. If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select unknown.

PATIENT STATUS

Current Device Strategy: This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant decision. This determination should be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter. The strategy should be selected as:

Bridge to recovery

Bridge to transplant– this is for a patient ALREADY listed for transplant or listed within 24 hours before device implantation

Possible bridge to transplant - *Likely to be eligible:* defines a patient in whom the transplant evaluation has not been completed but no contra-indications are anticipated, or in whom a current contra-indication is anticipated to resolve rapidly, such as recent infection

Possible bridge to transplant -*Moderate likelihood of becoming eligible:* similar to above, but with some potential concerns that might prevent eligibility.

Possible bridge to transplant -*Unlikely to become eligible:* should be used for a patient in whom major concerns have already been identified. These may not yet have been quantified, such as in a patient with known chronic lung disease without recent pulmonary function test measurement, or might be reversible, such as severe renal insufficiency or pulmonary hypertension that might improve after chronic mechanical support. It may be the expectation at the time of implant that the patient will most likely have the assist device as “permanent” or “destination” therapy.

Destination therapy (patient definitely not eligible for transplant). All factors that weigh in to the decision of non –transplant candidacy should be indicated below.

Other, specify type in the specification in the block provided.

Current Device Strategy:

Transplant Eligibility Issues or Contraindications to Transplant:

If you select Possible Bridge to Transplant or Destination Therapy, then check all that apply.

Checking these does not necessarily mean that a condition is a contra-indication. There are often many reasons why a patient is not an ideal candidate for transplantation, although it may still represent the best option for the patient. No specific thresholds are provided for these concerns or contra-indications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation.

Please go to Section 6.16 for information about the Adverse Event Reminder section of this form.

6.6 Implant Discharge

The **Implant Discharge Form** is to be completed at time of discharge from implant hospitalization **only if a VAD is in place and if the patient is still living at the time of discharge**. The measurements collected should be ones closest but prior to the implant discharge date.

If the VAD is explanted during the implant hospitalization due to transplantation or recovery, the discharge form is **not** required.

Chronology of Hospital Time Course

Enter **implant discharge date**: in mmddyyyy format. ***This is the discharge date from the VAD implant admission only.***

Select facility **Patient discharged to**: select one of the following facility types.

- Home - residential setting
- Nursing Home/Assisted Care
- Hospice
- Another hospital
- Rehabilitation Facility
- Unknown

Acute care (ICU / CCU) - duration of stay: type then number of days patient in Acute care (i.e. ICU/CCU). Days should not exceed number of days from implant date to implant discharge date. ST=unknown

Intermediate/step-down care - duration of stay: type the number of days patient in Intermediate care (i.e. Step Down care). Days should not exceed number of days from implant date to implant discharge date ST=unknown

Note: ICU/CCU duration + Intermediate/step-down duration cannot exceed the total days from implant date to implant discharge date.

approximate duration of inotropes: select the approximate time when patient stopped taking inotrope therapy from the list below:

- < 1 week
- 1-2 weeks
- 2-4 weeks
- > 4 weeks
- Unknown

Intervention since implant: select the type of intervention since VAD implant date from the list below.

- Surgical Procedure**
- Invasive Cardiac Procedures (Other than Heart Cath)
- Other
- None
- Unknown

If the intervention since VAD implant was **Surgical Procedure**: select the surgical procedure from the list below:

Device related operation – (if this is selected as the surgical procedure, please remember to go to the Device Malfunction Adverse Event form and complete.)

Other Cardiac Surgical Procedure

Non Cardiac Surgical Procedure

Other Procedure

Unknown

If the **Surgical Procedure** since the VAD implant was **Other Cardiac Surgical Procedure** intervention: select one of the following from the list below. If **Other specify** is selected, type in the specification in the block provided.

Reoperation for Bleeding within 48 hours of implant

Reoperation for Bleeding and/or tamponade > 48 hours

Surgical Drainage of pericardial effusion

Valve Surgery: Aortic Repair

Valve Surgery: Mitral Repair

Valve Surgery: Tricuspid Repair

Valve Surgery: Pulmonary Repair

Valve Surgery: Aortic Replacement - Mechanical

Valve Surgery: Aortic Replacement - Biological

Valve Surgery: Mitral Replacement - Mechanical

Valve Surgery: Mitral Replacement - Biological

Valve Surgery: Tricuspid Replacement - Mechanical

Valve Surgery: Tricuspid Replacement - Biological

Valve Surgery: Pulmonary Replacement - Mechanical

Valve Surgery: Pulmonary Replacement - Biological

Other, specify _____

Unknown

If the **Surgical Procedure** since the VAD implant was a **Non Cardiac Surgical Procedure** intervention: type the name of the Non-Cardiac Surgical Procedure in the block provided.

If the **Surgical Procedure** since the VAD implant was an **Other procedure** intervention: select one of the following from the list below. If **Other specify** is selected, type in the specification in the block provided

Reintubation due to Respiratory Failure

Dialysis

Bronchoscopy

Other, specify

HEMODYNAMICS

General Hemodynamics

Heart rate: beats per minute. ST= unknown or not done.

Systolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Diastolic bp: mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. ST= unknown or not done.

Volume status (peripheral edema): Volume status is determined from peripheral edema and ascites. Select one from none, mild, moderate, severe, unknown and not done. This would equate to 0, 1+, 2+ and 3-4+ would be severe.

Ascites: Yes, No or Unknown. This is in the clinicians' best guess, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

ECG rhythm (cardiac rhythm): Select one of the following. If **Other specify** is selected, type in the specification in the block provided.

- Sinus
- Atrial fibrillation
- Atrial flutter
- Paced
- Not done
- Other, specify
- Unknown

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. ST= Unknown or Not Done

Weight: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. ST= Unknown or Not Done

MEDICATIONS

Currently on IV inotrope therapy at discharge? Yes, No or Unknown.

If yes, IV inotrope therapy agents: Check all intravenous inotropes used at time of discharge. If **Other specify** is selected, type in the specification in the block provided.

Mark whether the medications listed are used at discharge: Yes, No or Unknown.

List of medications

Nesiritide

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

Beta-blockers

Aldosterone antagonist

Loop diuretics

Warfarin (coumadin)

Anteplatelet therapy drug – additionally, check all that apply.

Nitric oxide

If **Other specify** is selected, type in the specification in the block provided.

LABORATORY VALUES

Values closest to to time of discharge. For all of the tests listed below, give the appropriate measurement or check unknown or not done:

Blood urea nitrogen

Creatinine

Total bilirubin

Bilirubin direct

Bilirubin indirect

Sodium

INR

White blood cell count

Platelet

SGOT/AST

SGPT/ALT

Cholesterol

CRP (C Reactive Protein)

Potassium

Hemoglobin

Plasma free hemoglobin

Reticulocyte count

Patient has positive antiheparin/platelet antibody (HIT) – Yes, No, or Unknown

If yes, are they on direct thrombin inhibitors – Yes, No, or Unknown

If yes, check all that apply (aspirin, dipyridamole, plavix, heparin, coumadin, direct thrombin inhibitors)..

LDH
TEG profile, MA k
TEG profile, Rk
TEG profile, Rh
Protein C
Protein S
Anti-phospholipid (IgG)
Pre-albumin
Albumin

Institutions generally perform only one of the two following assays. The other one should be indicated as “not done”.

Brain natriuretic peptide BNP
NT pro brain natriuretic peptide Pro-BNP

DEVICE PARAMETERS

LVAD/TAH (left side) Device type Select Pulsatile or Rotary
RVAD/TAH (right side) Device type Select Pulsatile or Rotary or none

Device Parameters - Pulsatile

if LVAD/RVAD device selection is pulsatile, answer the following questions:

LVAD/TAH (left side) questions:

LVAD/TAH (left side) flow in liters per minute. ST= unknown or not done.

LVAD/TAH (left side) - pump drive pressure (pneumatic devices only) – mmHg (millimeters of Mercury) ST= unknown or not done.

LVAD/TAH (left side) control mode Select one of modes from the list provided.

Auto mode (or fill-to-empty)
 Fixed
 Unknown

LVAD/TAH (left side) – Fixed: Enter rate. ST= unknown or not done.

RVAD/TAH (right side) questions:

RVAD/TAH (right side) flow in liters per minute. ST= unknown or not done.

RVAD/TAH (right side) - pump drive pressure (pneumatic devices only) mmHg (millimeters of Mercury) ST= unknown or not done.

RVAD/TAH (right side) control mode: Select one of the modes from the list provided.

Auto mode (or fill-to-empty)
 Fixed

Unknown

RVAD/TAH (right side) – Fixed: Enter rate. ST= unknown or not done.

Device Parameters - Rotary

if LVAD/RVAD device selection is Rotary, answer the following questions

LVAD/TAH (left side flow) in liters per minute. ST= unknown or not done.

LVAD/TAH (left side pump speed) – revolutions per minute

LVAD/TAH (left side power (watts)) – enter watts

LVAD/TAH (left side current (amps)) – enter amps

RVAD/TAH (right) side flow in liters per minute. ST= unknown or not done.

RVAD/TAH (right) side pump speed - revolutions per minute

RVAD/TAH (right) side power (watts) - enter watts

RVAD/TAH (right) side current (amps) – enter amps

Note:

No QUALITY OF LIFE/Trail Making Test (Part B) at Implant Discharge.

Please go to Section 6.16 for information about the Adverse Event Reminder section of this form.

6.7 Rehospitalization

The **Rehospitalization Form** is to be collected at 1 week from discharge.

Enter **date of admission:** in mmddyyyy format. ST=Unknown.

Enter **discharge date:** in mmddyyyy format. ***This is the discharge date associated with this rehospitalization admission only.*** ST=Unknown.

Check all **reasons for admission** that apply from the list below. If **Planned Procedure** is selected, please type the planned procedure in the block provided. If **Other** is selected, please type other reason for admission in the block provided.

- Cardiac Arrhythmia
- Bleeding
- Cardiac Tamponade
- Hematoma
- Hemolysis
- Hepatic Dysfunction
- Hypertension
- Infection - go to AE Infection Form
- GI Disorder

Pulmonary Disorder
 Limb vascular complication
 Pulmonary Embolism/Hemorrhage
 Planned Procedure, specify _____
 Device Malfunction - go to AE Device Malfunction Form
 Myocardial infarction
 Neurological Dysfunction - go to AE Neurological Dysfunction Form
 Psychiatric episode
 Renal Dysfunction
 Right Heart Failure
 Non-CNS Thromboembolic (TE) Event
 Wound Complication
 Unknown
 Other

Rehospitalization Intervention: select the type of rehospitalization intervention from the list below

Surgical Procedure

Heart Cath
 Invasive Cardiac Procedures (Other than Heart Cath)
 Other
 Unknown

If the rehospitalization intervention was **Surgical Procedure:** select the surgical procedure from the list below:

Device related operation – (if this is selected as the surgical procedure, please remember to go to the Device Malfunction Adverse Event form and complete.)

Other Cardiac Surgical Procedure
Non Cardiac Surgical Procedure
 Other Procedure
 Unknown

If the Rehospitalization **Surgical Procedure** was an **Other Cardiac Surgical Procedure** intervention: select one of the following from the list below. If **Other specify** is selected, type in the specification in the block provided.

Valve Surgery: Aortic Repair
 Valve Surgery: Mitral Repair
 Valve Surgery: Tricuspid Repair
 Valve Surgery: Pulmonary Repair
 Valve Surgery: Aortic Replacement - Mechanical
 Valve Surgery: Aortic Replacement - Biological
 Valve Surgery: Mitral Replacement - Mechanical
 Valve Surgery: Mitral Replacement - Biological
 Valve Surgery: Tricuspid Replacement - Mechanical
 Valve Surgery: Tricuspid Replacement - Biological

Valve Surgery: Pulmonary Replacement - Mechanical
 Valve Surgery: Pulmonary Replacement – Biological
 Device Replacement
 Unknown
 Other, specify _____

If the Rehospitalization **Surgical Procedure** was a **Non Cardiac Surgical Procedure** intervention: type the name of the Non-Cardiac Surgical Procedure in the block provided.

If the rehospitalization intervention was **Heart Cath:** enter the following measurements as provided.

Enter CVP: in mm/Hg. ST= Unknown or not done

Enter PA systolic pressure: in mm/Hg. ST= Unknown or not done

Enter PA diastolic pressure: in mm/Hg. ST= Unknown or not done

Enter PCW pressure: in mm/Hg. ST= Unknown or not done

Enter Cardiac Output: in L/min. ST= Unknown or not done

Please go to Section 6.16 for information about the Adverse Event Reminder section of this form.

6.8 AE Device Malfunction

Device Malfunction

Device malfunction denotes a failure of one or more of the components of the MCSD system which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. The manufacturer must confirm device failure. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.

Device failure should be classified according to which components fails as follows:

1) **Pump** failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of **pump thrombosis**, thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure.

2) **Non-pump** failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)

The **Adverse Event: Device Malfunction Form** is to be collected at time of event.

Definition: The inability of the Mechanical Circulatory Support System to maintain adequate circulatory support which requires hospitalization

Enter **Device Type:** select appropriate device type for this device malfunction event:

LVAD

RVAD

Both (in the same OR visit)

Enter **date of onset** of adverse event; in mmddyyyy format.

Location of patient : select whether patient was in or out of hospital at time of adverse event. If location was not known, select unknown.

Major pump unit involved: check all pump units that apply with this adverse event.

- Blood Pump
- Drive Unit Failure
- External Control System Failure
- Device Thrombosis

For each major pump unit selected a text box will appear at the bottom of the list where you may enter details concerning this adverse event relating to the particular major pump unit selected.

Specific component affected: select all components affected that apply to this adverse event. If **Other component malfunction, specify** is selected, type in the specification in the block provided

- External Battery Malfunction
- Internal Battery Malfunction
- External Controller Malfunction
- Internal Controller Malfunction
- Driveline Malfunction
- Inflow Graft Malfunction/Malposition
- Outflow Graft Malfunction/Malposition
- Pump Drive Unit Malfunction
- TET System Malfunction
- Inflow Valve
- Outflow Valve
- Volume Compensator Malfunction
- Other Component Malfunction, specify _____

For each specific component affected that is selected a text box will appear at the bottom of the list where you may enter details concerning this adverse event relating to the particular component affected.

Causative or contributing factors to the device malfunction: select all causes or contributing factors that apply to this adverse event.

- Patient noncompliance in device maintenance and protection
- Patient error in caring for system
- Inadequate instructions from caregivers
- No specific contributing cause identified

Device malfunction intervention: select all device interventions that apply to this adverse event. If **Replacement of Other Component, specify** is selected, type in the specification in the block provided. If **Other Interventions, specify** is selected, type in the specification in the block provided

- Replacement of External Battery
- Replacement of Internal Battery

Replacement of External Controller
 Replacement of Internal Controller
 Replacement of Driveline
 Replacement of Inflow Graft
 Replacement of Outflow Graft
 Replacement of Pump
 Replacement of TET System
 Replacement of Pump Valve
 Replacement of Volume Compensator
 Replacement of Other Component, specify
 Switch from Vented Electric to Pneumatic-mode
 Other Interventions, specify
 None
 Unknown

Surgical procedure required? If a surgical procedure was required in this device malfunction adverse event, answer Yes and remember to fill out surgical intervention on the Rehospitalization Form. If no surgical procedure was required then answer No. If it is not known if surgical procedure required, select Unknown.

Device explanted: Was device explanted at this event? If so, then answer Yes and fill out the Explant form. If the device was not explanted at this event, then answer No. If it is unknown whether device was explanted at this event, then answer Unknown.

Device malfunction adverse event cause patient's death: Did this device malfunction adverse event cause the patient's death, then answer Yes. If it did not cause the patient's death, then answer No. If it is not known if this device malfunction adverse event caused this patient's death, then answer Unknown.

6.9 AE Infection

Major Infection

A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

Localized Non-Device Infection

Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (see sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Pocket Infection

A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy, when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection

Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

Sepsis

Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.

The **Adverse Event: Major Infection Form** is to be collected at time of event.

Definition: Evidence of infectious process requiring antibiotic therapy occurring in or requiring hospitalization

Enter **date of onset** of adverse event; in mmddyyyy format.

Location of patient : select whether patient was in or out of hospital at time of adverse event. If location was not known, select unknown.

Location of infection: select all locations of infection that apply to this adverse event. If **Other specify** is selected, type in the specification in the block provided

- Pump / related - Drive Line
- Pump / related - Pump Pocket
- Pump / related - Pump Interior
- Positive Blood cultures
- Line Sepsis
- Pulmonary
- Urinary Tract
- Mediastinum
- Peripheral Wound
- GI
- Unknown
- Other, specify _____

Type of infection: select one of the following types of infection.

- Bacterial
- Fungal
- Viral
- Potozoan
- Unknown

Causative or contributing factors to the infection AE: Check all causes or contributing factors relating to this adverse event

- Patient condition
- Patient non-compliance with Medications
- Patient non-compliance with Device Maintenance
- Patient non-compliance with Followup Visits
- Device related
- Complexities of Medical Management
- Unknown

Intervention: select one of the following interventions used for this adverse event.

- Drug therapy only
- Surgical and drug therapy (reminder: fill out surgical interventions on rehospitalization form)
- Surgical therapy only (reminder: fill out surgical interventions on rehospitalization form)
- Unknown

Did this infection contribute to death?: Enter Yes if this infection contributed to the death of this patient. Enter No if this infection did not contribute to the death of this patient. If not known, select Unknown.

6.10 AE Neurological Dysfunction

Neurological Dysfunction

Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard neurological examination (administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note). The examining physician will distinguish between a transient ischemic attack (TIA), which is fully reversible within 24 hours (and without evidence of infarction), and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). The NIH Stroke Scale (for patients > 5 years old) must be re-administered at 30 and 60 days following the event to document the presence and severity of neurological deficits. Each neurological event must be subcategorized as:

- 1) Transient Ischemic Attack (acute event that resolves completely within 24 hours with no evidence of infarction)
- 2) Ischemic or Hemorrhagic Cardiovascular Accident/CVA (event that persists beyond 24 hours or less than 24 hours associated with infarction on an imaging study).

In addition, to above, for patients < 6 months of age, any of the following:

- 3) New abnormality of head ultrasound
- 4) EEG positive for seizure activity with or without clinical seizure

h

e Adverse Event: Neurological Dysfunction Form is to be collected at time of event

Definition: Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard examination which requires hospitalization

Enter **date of onset** of adverse event; in mmddyyyy format.

Location of patient : select whether patient was in or out of hospital at time of adverse event. If location was not known, select unknown.

Neurological Dysfunction Categories: Select one of the neurological dysfunction categories. If **Neurological Dysfunction - Other** is selected, type in the specification in the block provided

Neurological Dysfunction - < 24 hours

Neurological Dysfunction - > 24 hours

If patient < 6 months, new abnormality of head ultrasound

If patient < 6 months, positive EEG

Neurological Dysfunction - other

Causative or contributing factors to the Neurological Dysfunction AE: select all causes or contributing factors that apply to this Neurological dysfunction adverse event.

Patient not taking anticoagulation medication properly

If patient receiving warfarin then, evidence of INR above target range

If patient receiving warfarin then, evidence of INR below target range

If patient receiving heparin, evidence of INR above target range

If patient receiving heparin, evidence of INR below target range

Complexities of Medical Management

Unknown

Details of CNS event: select one of the neurological dysfunction details. If **Other** is selected, type in the specification in the block provided

Intracranial Bleed
Embolism
Other

Location of CNS event: select one of the neurological dysfunction event locations from the list provided. If **Other specify** is selected, type in the specification in the block provided

Right hemisphere
Left hemisphere
Occipital
Brain stem
Unknown
Other, specify _____

Method of Diagnosis of CNS event: select one of the methods of diagnosis of the neurological dysfunction event from the list provided. If **Other specify** is selected, type in the specification in the block provided

CT
MRI
Angiogram
Clinical
Unknown
Other, specify _____

Description of Clinical Event: select one description of neurological dysfunction clinical event from the list provided.

Stroke
Seizure
unknown

If description of clinical event is **Stroke** select one **stroke severity** from the list provided. If **Other specify** is selected, type in the specification in the block provided

Left sided weakness
Right sided weakness
Left sided paralysis
Right sided paralysis
Speech deficit
Altered mental status
Coma
Other, specify

Anticoagulant therapy at time of event: if anticoagulant therapy was used at the time of this event, check all therapies that apply. If **Other specify** is selected, type in the specification in the block provided

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

Surgical intervention: If there was surgical intervention at the time of this event, answer Yes and fill out the surgical intervention portion of the Rehospitalization Form. If no surgical intervention at the time of this event, then answer No. If it is unknown if surgical intervention applied at the time of this event, answer Unknown.

Drug intervention: If there was drug intervention at the time of this event, answer Yes and answer treatment question that follows. If no drug intervention was used at the time of this event, then answer No. If it is unknown if drug intervention used at the time of this event, answer Unknown.

Treatment: If drug intervention was used at the time of this event, then check all drug treatments that apply to this event from the list provided

- Heparin
- Thrombolytics
- Anti-Seizure
- None of the above

Did this Neurological Dysfunction Adverse Event contribute to the patient's death? If this adverse event caused or contributed to this patient's death, answer Yes. If this adverse event did not cause or contribute to this patient's death, answer No. If not known, select Unknown.

6.11 Explant – Transplant

The **Explant Form** is to be collected at time of explant or transplant or both.

Enter **Device explanted:** select appropriate device type for this explant event:

LVAD

RVAD

Both (in the same OR visit)

Explant date: enter explant date in mmddyyyy format.

Explant reason: select one of the following as the reason for explant. If **other, specify** is selected, type in the specification in the block provided.

Transplant - *Enter Transplant Date and Waitlist ID below*

Death - *go to Death Form*

Device Malfunction - Elective - *go to AE Device Malfunction Form*

Device Malfunction - Emergent - *go to AE Device Malfunction Form*

Ventricular Recovery/Wean

Other, Specify

Note: If patient is transplanted, that patient will no longer be followed in the INTERMACS Registry, but will be followed in UNOS web based data entry for transplant system. If the patient is explanted due to ventricular recovery, INTERMACS will continue a 1 year follow-up for this patient for death and/or transplant .

If patient was explanted at time of transplant enter transplant date: enter the transplant date in mmddyyyy format.

If patient was explanted at time of transplant enter Waitlist ID: UNOS waitlist identifier.

6.12 Death

The **Death Form** is to be collected at time of death.

Enter **death date:** in mmddyyyy format.

Device functioning normally: if the device was functioning normally at time of death, select Yes. If the device was not functioning normally at time of death, select No and fill out the Device Malfunction Adverse Event Form. If it is not known whether the device was functioning normally at time of death, select Unknown.

Post mortem device explant: Was the device explanted post mortem? Yes, No or Unknown.

If post mortem device explanted, **did device go to manufacturer:** Yes, No or Unknown

Location of death : select whether patient was in or out of hospital at time of death. If location was not known, select unknown.

Timing of death: select one of the timings of death: Expected, Unexpected or the timing of death was Unknown.

Autopsy: Was an autopsy performed? Yes, No or Unknown.

Primary cause of death: select one primary cause of death from the list provided.

Arterial embolism
 Cancer
 Cardiovascular Myocardial Infarction
 Cardiovascular: Other, Specify
 Device Malfunction *go to AE Device Malfunction Form*
 Fluid/Electrolyte Disorder
 Hematologic: Other, Specify
 Hemorrhage: Disseminated Intravas Coagulation
 Hemorrhage: Gastrointestinal
 Hemorrhage: Intraoperative
 Hemorrhage: Other, Specify
 Hemorrhage: Post-Operative surgery related
 Hemorrhage: Pulmonary
 Infection *go to AE Infection Form*
 Intraop: Not Hemorrhage specify
 Liver Failure
 Other chronic illness, specify
 Pancreatitis
 Pulmonary: Pulmonary Embolism
 Pulmonary: Respiratory Failure
 Pulmonary: Other, specify
 Renal Failure
 Ruptured Aortic aneurysm
 RV failure
 Sudden unexplained death
 Suicide
 Trauma/accident, specify
 Vtach/Vfib
 Other, specify
 Unknown
 CNS cause of death` *go to AE Neuro Dys Form*

If **Trauma/accident specify** is selected, type in the specification in the block provided.

If **Cardiovascular: other, specify** is selected, type in the specification in the block provided.

If **Pulmonary: other, specify** is selected, type in the specification in the block provided.

If **Hemorrhage: other, specify** is selected, type in the specification in the block provided.

If **Intraop: not hemorrhage - other, specify** is selected, type in the specification in the block provided.

If **Hematologic: other, specify** is selected, type in the specification in the block provided.

If **Other chronic illness, specify** is selected, type in the specification in the block provided.

If **Other, specify** is selected, type in the specification in the block provided.

If **primary cause of death** selected is **cancer**, select the type of cancer from the list provided. If **other, specify** is selected, type in the other cancer specification in the block provided.

CNS
GI
Lymph
ENT
Pulmonary
Renal
Breast,
Reproductive,
Skin,
Other
Unknown

Contributing cause of death: check all contributing causes of death from the list provided.

Two Contributing or secondary causes of death can be entered. If no contributing or secondary cause of death, select NONE.

Arterial embolism
Cancer
Cardiovascular Myocardial Infarction
Cardiovascular: Other, Specify
Device Malfunction *go to AE Device Malfunction Form*
Fluid/Electrolyte Disorder
Hematologic: Other, Specify
Hemorrhage: Disseminated Intravas Coagulation
Hemorrhage: Gastrointestinal
Hemorrhage: Intraoperative
Hemorrhage: Other, Specify
Hemorrhage: Post-Operative surgery related
Hemorrhage: Pulmonary
Infection *go to AE Infection Form*
Intraop: Not Hemorrhage specify
Liver Failure
Other chronic illness, specify
Pancreatitis
Pulmonary: Pulmonary Embolism
Pulmonary: Respiratory Failure

Pulmonary: Other, specify
 Renal Failure
 Ruptured Aortic aneurysm
 RV failure
 Sudden unexplained death
 Suicide
 Trauma/accident, specify
 Vtach/Vfib
 Other, specify
 Unknown
 CNS cause of death`

go to AE Neuro Dys Form

If **Trauma/accident specify** is selected, type in the specification in the block provided.

If **Cardiovascular: other, specify** is selected, type in the specification in the block provided.

If **Pulmonary: other, specify** is selected, type in the specification in the block provided.

If **Hemorrhage: other, specify** is selected, type in the specification in the block provided.

If **Intraop: not hemorrhage - other, specify** is selected, type in the specification in the block provided.

If **Hematologic: other, specify** is selected, type in the specification in the block provided.

If **Other chronic illness, specify** is selected, type in the specification in the block provided.

If **Other, specify** is selected, type in the specification in the block provided.

If **primary cause of death** selected is **cancer**, select the type of cancer from the list provided. If **other, specify** is selected, type in the other cancer specification in the block provided.

CNS
 GI
 Lymph
 ENT
 Pulmonary
 Renal
 Breast,
 Reproductive,
 Skin,
 Other
 Unknown

Please go to Section 6.16 for information about the Adverse Event Reminder section of this form.

6.13 Quality of Life

The **EuroQoL Questionnaire** is provided in **Appendix F of the protocol**.

Quality of life is to be measured by the EURoQoL (EQ-5D) instrument. Only adult patients (age 19 years and older, at time of implant) will be asked to complete this instrument. Currently, pediatric patients are not to complete a quality of life instrument. EURoQoL (EQ-5D) is to be administered pre-implant and post-implant (3 months, 6 months, and q 6 months thereafter).

Patient Consent

- Pre-implant: If INTERMACS consent is obtained before MCS D implant, administer the pre-implant EURoQoL as soon as possible after obtaining consent.
- Post-implant: If INTERMACS consent is obtained after MCS D implant, the pre-implant EURoQoL is not to be administered. Administer the first post-implant EURoQoL at 3 month follow-up time point.

Data collection

The EURoQoL (EQ-5D) is administered by research or clinical coordinators as designated by each participating medical center. The EURoQoL (EQ-5D) instrument can be printed from the INTERMACS website www.intermacs.org or from this manual.

Pre-implant data collection

The patient is to complete the EURoQoL before-MCS D implant (if feasible and consent is granted).

Post-implant data collection (3, 6, and q 6 months post implant)

- The patient is to complete the instrument at the return clinic visits closest to the appropriate data collection time points (given the patient has been discharged prior to the data collection time points)
- Patients that remain hospitalized at the 3, 6 or 12 month time point should complete the EURoQoL, if able
- Coordinators enter EURoQoL results or the **Missing QOL Data Form** into INTERMACS

Instrument Administration

- The patient is to complete the QOL instrument independently.
- If the patient is unable to complete the QOL instrument, the coordinator or a family member is to read the questions to the patient and complete the instrument documenting the patient's responses. Indicate on the instrument that the EURoQoL was self-administered or administered verbally by another.
- There should be no coaching regarding responses.

- Enter the patient's answers from the paper form into the database through www.intermacs.org.

Data Screening

- The EURoQoL is to be reviewed for missing or unclear data at the time of instrument completion. Corrections must be made with the patient at that time.

Non Submission of EURoQoL

- For patients who do not complete the EURoQoL, a **Missing QOL Data Form** is completed by the coordinator for each missed time period. The **Missing QOL Data Form** is printable from the INTERMACS website www.intermacs.org or from this manual.

6.14 Neurocognitive function test

The **Trail-Making Sample B and Part B** are provided in **Appendix G of the protocol**.

Neurocognitive function is to be measured by the Trail-Making Part B test. Only adult patients (age 19 years and older, at time of implant) will be asked to complete this test. Currently, pediatric patients are not to complete a neurocognitive function test. Trail-Making Part B is to be administered **pre-implant** and **post-implant** (3 months, 6 months, and q 6 months thereafter).

After the subject completes Part B, take the test sheet and record the time in seconds. Errors contribute to the evaluation of the performance principally by increasing the total performance time. If the patient completes the test but the test is considered invalid, select "completed but invalid (score not entered)". **Do not allow patient to retake the test.**

Administering the test

1. Let patient practice with Sample B

Script:

"On this page are some numbers and letters. Begin at 1 (point) and draw a line from 1 to A" (Point to A) "A to 2,"(Point to 2), "2 to B" (point to B), "B to 3" (point to 3), "3 to C" (point to C), "and so on, in order, until you reach the end" (point to the circle marked "end").

Then say:

"Remember, first you have a number" (point to 1), "then a letter" (point to A), "then a number" (point to 2), "then a letter" (point to B), "and so on. Draw the lines as fast as you can. Ready--- Begin!"

If the subject completes the sample B correctly say: *"Good! Let's try the next one."* Proceed immediately to Part B. **If the subject makes a mistake on sample B, point out the error and explain why it is incorrect.** The following explanations of mistakes serve as illustrations:

"You started with the wrong circle. This is where you start (point to 2. "You skipped this circle" (point to the circle the subject omitted). "You should go from 1" (point to 1) "to A" (point to A), "A to 2" (point to 2), "2 to B" (point to B), "B to 3" (point to 3) "and so on until you reach the circle marked 'end'." (point)

If the subject cannot complete Sample B, take his/her hand and guide the pencil, using the eraser end, through the circles. Then say:

"Now you try it. Remember, you begin at number 1" (point) "and draw a line from 1 to A" (point to A), "A to 2" (point to 2), "2 to B" (point to B), "B to 3" (point to 3), "and so on until you reach the circle marked "end" (point). "Ready --- Begin!"

2. Ask patient to complete Part B

If the subject succeeds this time, go on to Part B. If not repeat the procedure until the task is performed successfully or it becomes evident that the subject cannot do the task.

After the subject has completed the sample, turn the paper over to Part B and say:

"On this page are both numbers and letters. Do this the same way. Begin at number 1" (point to 1) "and draw a line from 1 to A" (point to A), "A to 2" (point to 2), "2 to B" (point to B), "B to 3" (point to 3), "3 to C" (point to C), "and so on, in order, until you reach the end" (point to the circle marked "end"). "Remember, first you have a number" (point to 1), "then a letter" (point to A), "then a number" (point to 2), "then a letter" (point to B), "and so on. Do not skip around, but go from one circle to the next in the proper order. Draw the lines as fast as you can. Ready ---Begin!"

Using the stopwatch, start timing as soon as the subject is told to begin. Remember to be alert for mistakes. If the subject makes an error, DO NOT STOP TIMING. Point it out immediately, return the subject to the last correct circle and say: *"Now, are you looking for a number or a letter?"* Continue the test from that point. Do not stop timing.

After the subject completes Part B, take the test sheet and record the time in seconds. Errors contribute to the evaluation of the performance principally by increasing the total performance time. If the patient completes the test but the test is considered invalid, select "other, specify" and, specify the reason you are not entering a score. **Do not allow patient to retake the test.**

6.15 Blood and Tissue Specimens (optional)

The **Blood and Tissue Standard Operating Procedures** are provided in **Appendix H of the protocol**. Blood and Tissue Samples are to be taken during the implant and explant surgeries.

Patient consent:

Many IRB's require that patients have the opportunity to consent separately for DNA testing. Please select yes or no by the type of testing to which the patient gave consent.

Patient consents to the use of his/her specimens for general heart failure tests. Yes or No

Patient consents to the use of his/her specimens for DNA testing. Yes or No

Myocardial tissue obtained:

Was left ventricular myocardial tissue obtained? Select Yes, No, or Unknown. If Yes, continue the Ventricular Tissue questions that follow.

During Implant or Explant? Select one.

Enter the **date** the tissue was obtained in mm/dd/yyyy format.

Enter the **biological sample inventory code (BSI#)** that appears on the pre-printed labels from the kit provided by the NHLBI repository. ST=Unknown

<p>AJ010000 001 SNAP FROZEN AC Implant</p> <p>Date of Implant</p> <p>-----/-----/----- -</p>

← SAMPLE LABEL

The first 8 digits (shown here in blue) are the **Biological Sample Inventory number** (BSI#).

The last 3 digits (shown here in red) are the **Sequence number**.

Tissue processing: check all tissue processes that apply. It is recommended that your center perform both snap

frozen and formalin procedures as outlined in the standard operating procedures.

Snap frozen

Formalin

Unknown

Venus blood obtained: was blood obtained? Select Yes, No, or Unknown. If Yes, continue the Blood questions that follow.

Enter the **date** the blood was obtained in mm/dd/yyyy format.

Enter the **(biological sample inventory code – BSI#)**. ST=Unknown – *Note: The BSI# will be the same for both (1) tissue and (2) blood if they were obtained from the patient during the same implant/explant procedure.*

Blood processing: check all blood processes that apply. It is recommended that your center perform both buffycoat and serum procedures as outlined in the standard operating procedures.

6.16 Adverse Event Reminders

The **Adverse Event Reminders** are collected at the following intervals and/or events: All adverse event definitions are listed in **Appendix A** of the Protocol located at the INTERMACS website, you may also click the web-link provided on the web-based data entry screen(s) at the following intervals which will open Appendix A for reference.

- 1 week post implant
- 1 month post implant
- 3 months follow up
- Every 6 months follow up
- Implant Discharge
- Rehospitalization
- Death

Note: Adverse Events Infection, Device Malfunction and Neurological Dysfunction are separate forms. These definitions are listed within its adverse event section

MAJOR BLEEDING episode: Did patient (if ≥ 50 kg) require ≥ 2 units or (if < 50 kg) require ≥ 10 cc/kg of packed red blood cells (p.c.) after 7 days following implant or since last INTERMACS report/last follow-up? Yes, No, or Unknown

If yes, enter **Date patient received p.c.** in mmddyyyy format

If yes, **Approximate # of units p.c. received?**

- 2-3 units
- 4-7 units
- 8 or more units
- If patient < 50 kg, 10-19 cc/kg
- If patient < 50 kg, 20-39 cc/kg
- If patient < 50 kg, ≥ 40 cc/kg
- Unknown

If yes, **Anticoagulant therapy at time of event:** check all that apply:

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran

None

Other - - if selected, enter in block provided

CARDIAC ARRHYTHMIA **Did a documented arrhythmia result in clinical compromise since last INTERMACS report/last followup?** Yes, No or Unknown

If yes, enter **Date of event** in mmddyyyy format

If yes, Enter **Type of arrhythmia** from selection below:

Sustained ventricular arrhythmia requiring defibrillation or cardioversion

Sustained supraventricular arrhythmia requiring drug treatment or cardioversion

Unknown

PERICARDIAL FLUID COLLECTION **Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?** Yes, No or Unknown

If yes, enter **Date of event** in mmddyyyy format

If yes, were there **Signs of tamponade?** Yes, No or Unknown

If yes, **Method of Drainage** – OP, Cath, or Unknown

HEMOLYSIS: Did clinical signs associated with hemolysis [plasma-free hemoglobin (PFHgb) > 40 mg/dl] occur after the first 72 hours post-implant or since last INTERMACS report/last follow up?

If yes, **Enter Plasma-Free Hemoglobin measurement** in mg/dL

If yes, **Enter Hematocrit measurement** percent

If yes, **Does patient have Hyperbilirubinemia (Total Bilirubin > 2 mg/dl)?**
Yes, No or Unknown

If yes, enter **Cause of Hemolysis**

Device-related

Other, specify – if selected, enter in block provided

Unknown

HEPATIC DYSFUNCTION: Did clinical evidence of liver dysfunction occur since last INTERMACS report/last followup beyond 14 days post implant? Yes, No, or Unknown.

If yes, **Enter total bilirubin measurement:** as mg/dL

If yes, **Enter SGOT/AST measurement:** as U/L

If yes, **Enter SGPT/ALT measurement:** as U/L

This reminder is not collected at 1-week follow up

HYPERTENSION: Did onset bp \geq 140mm Hg systolic or 90mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump) (Pediatric patient: $>$ 95th percentile – See definition) occur since last INTERMACS report/last followup?

Yes, No, or Unknown

If yes, **Enter systolic bp:**

If yes, **Enter diastolic bp:**

MYOCARDIAL INFARCTION Did a myocardial infarction occur since last INTERMACS report/last follow-up? Yes, No, and Unknown

If yes, **list date of event** in mmddyyyy format.

PSYCHIATRIC EPISODE: Did a disturbance in thinking, emotion or behavior occur that required intervention since last INTERMACS report/last followup? Yes, No, and unknown.

RENAL DYSFUNCTION: Did a renal dysfunction requiring dialysis occur since last INTERMACS report/last followup? Yes, No, and unknown.

If yes, enter **Date of event** in mmddyyyy format

If yes, **Enter dialysis duration** in number of weeks.

If yes, **Enter peak creatinine measurement**

RESPIRATORY FAILURE: Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup? Yes, No, or Unknown

If yes, **Enter date of event** in mmddyyyy format.. **ST= unknown or ongoing**

If yes, **Enter Intubation duration in days.** **ST= unknown or ongoing**

If yes, **Was a trachotomy performed?** Yes, No, or Unknown

RIGHT HEART FAILURE: Did symptoms or signs of right heart failure requiring RVAD implantation; or requiring inhaled nitric oxide or inotropic therapy for a duration of more than 1 week at any time after LVAD implantation or since last update? Yes, No, or Unknown.

If yes, enter **Date of event** in mmddyyyy format

If yes, **Check all signs/symptoms that apply:**

CVP > 18 mmHg
CI < 2.0 L/min/M²
Ascites
Peripheral to Edema

This reminder is not collected at 1-week follow up

ARTERIAL NON-CNS THROMBOEMBOLISM: Did an acute perfusion deficit in any non-cerebrovascular organ system occur since lastINTERMACS report/last followup? YES, No, or Unknown.

If yes, **Enter date** in mmddyyyy format

If yes, **Select one location:**

Pulmonary
Renal
Hepatic
Splenic
Limb
Other - if selected, enter in block provided
Unknown

If yes, **Enter Confirmation source:**

Standard clinical and laboratory testing
Operative findings
Autopsy finding
Other – if selected, enter in block provided
Unknown

If yes, **Anticoagulant therapy at time of event:** check all that apply

Warfarin
Heparin
Lovenox
Aspirin
Dipyridamole
Clopidogrel (plavix)
Argatroban
Bilvalirudin
Fondaparinux
Hirudin
Lepirudin
Ximelagatran
None
Other - if selected, enter in block provided

VENOUS THROMBOEMBOLIC EVENT: Was there evidence of Venous Thromboembolic event since last INTERMACS report/last followup? Yes, No, or Unknown

If yes, **check all that apply:**

Deep Vein thrombosis – enter date in mmddyyyy format

Pulmonary Embolis – enter date in mmddyyyy format

Other – if selected, enter in block provided

Unknown

If yes, **Anticoagulant therapy at time of event:** check all that apply:

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bilvalirudin

Fondaparinux

Hirudin

Lepirudin

Ximelagatran

None

Other – if selected, enter in block provided

WOUND DEHISCENCE: Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup? Yes, No, or Unknown

If yes, **Enter date** in mmddyyyy format.

Other Major Serious Adverse Event: enter other serious adverse event that occurred since last INTERMACS report/last follow-up into the block provided

This page intentionally left blank.

Appendix V

INTERMACS Electronic Data Form

INTERMACS Eligibility

Please submit the data below to confirm eligibility for INTERMACS inclusion. Only enter information on consented patients with FDA approved durable (potential for patient discharge) devices. FDA approved temporary devices should be included only if they are implanted simultaneously with a durable device or subsequent to a durable device.

Note: If a patient is part of an FDA pre-approval study, then the patient should not be entered into INTERMACS even if he/she receives an approved device as part of the study.

Device type:*	<input type="text"/>
Device brand:*	<input type="text"/>
Device brand (RVAD):*	<input type="text"/>
Specify:*	<input type="text"/>
Specify RVAD:*	<input type="text"/>
Implant date:*	<input type="text"/> mm/dd/yyyy



Add a New Patient

To begin complete the following required fields to enter a new patient into the system.

Institution*

First name:*

Middle initial:

Last name:*

Medical record number:

SSN (last 5 digits)* ST=

Date of birth:*

Gender:* Male Female Unknown

Ethnicity: Hispanic or Latino:* YES NO

Race: select as many as apply:* American Indian or Alaska Native
 Asian
 African-American or Black
 Hawaiian or other Pacific Islander
 White
 Unknown/Undisclosed
 Other/none of the above

Marital status:*

Highest education level:*

Academic progress:*

Academic activity level:*

Working for income:* YES NO UNK

If No, Not Working Due To: *

If Yes: *



pre implant

Pre-Implant

Demographics

Height:* in cm

ST =

Weight:* lbs kgs

ST =

Blood type:*

Medical Support Status

Current device strategy:*

Specify:*

Transplant Eligibility Issues or Contraindications to Transplant - check all that apply*

- Advanced age
- Fixed pulmonary hypertension
- Patient refuses transplant
- Contraindication to immunotherapy
- Frailty
- Malnutrition/cachexia
- Large BMI
- Musculoskeletal limitations
- History of solid organ cancer
- History of lymphoma, leukemia
- Major stroke
- Renal dysfunction
- Pulmonary disease
- Severe diabetes
- Peripheral vascular disease
- Other comorbidity
- Risk of recurrent infection
- Pulmonary hypertension
- Recent pulmonary embolus
- Allosensitization

- Heparin-induced thrombocytopenia
- Current infection
- Limited cognition/understanding
- Limited social support
- Illicit drug use
- Alcohol abuse
- Still smoking
- Severe depression
- Other major psychiatric diagnosis
- Repeated non-compliance
- Multiple sternotomies
- Mediastinal radiation
- Thoracic aortic disease
- Other, specify
- None

Other, specify:*

Implant decision date:*

 mm/dd/yyyy

ST=

Time since first cardiac diagnosis:*

Primary cardiac diagnosis:*

Dilated Myopathy Specify:*

Restrictive Myopathy Specify:*

Select all that apply:*

- Complete AV Septal Defect
- Congenitally Corrected Transposition
- Ebstein's Anomaly
- Hypoplastic Left Heart
- Left Heart Valvar/Structural Hypoplasia
- Pulmonary Atresia with IVS
- Single Ventricle
- TF/TOF variant
- Transposition of the Great Arteries
- Truncus Arteriosus
- VSD/ASD
- VSD/ASD Other, specify
- Kawasaki Disease

Secondary cardiac diagnosis
(check all that apply):*

Other, specify

Unknown

Specify: *

VSD/ASD Specify: *

Cancer

Congenital Heart Disease

Coronary Artery Disease

Dilated Myopathy: Adriamycin

Dilated Myopathy: Alcoholic

Dilated Myopathy: Familial

Dilated Myopathy: Idiopathic

Dilated Myopathy: Ischemic

Dilated Myopathy: Myocarditis

Dilated Myopathy: Other Specify

Dilated Myopathy: Post partum

Dilated Myopathy: Viral

Hypertrophic cardiomyopathy

Restrictive Myopathy: Amyloidosis

Restrictive Myopathy: Endocardial Fibros

Restrictive Myopathy: Idiopathic

Restrictive Myopathy: Other specify

Restrictive Myopathy: Sarcoidosis

Restrictive Myopathy: Sec to Radiat/Chem

Valvular Heart Disease

Unknown

None

Dilated Myopathy Specify: *

Restrictive Myopathy Specify: *

Known cardiac biopsy: *

Specify: *

Previous cardiac operation (check
all that apply):*

None

CABG

Aortic Valve replacement / repair

Mitral valve replacement / repair

- Congenital card surg
- LVAD
- RVAD
- TAH
- Other, specify

Specify:*

If congenital cardiac surg then check all that apply:*

- Norwood Stage I
- PA Banding
- TOF/DORV/RVOTO Repair
- VSD Repair
- Transposition of the Great Vessels Repair
- Truncus Arteriosus Repair
- Valve Replacement of Repair for Outflow Obstruction
- AP Shunt
- ASD Repair
- Complete AV Septal Defect Repair
- Congenitally Corrected Transposition Repair
- Damus Kaye Stansel (DKS)
- Estein's Anamoly Repair
- Fontan
- Glenn, Bi-directional
- Glenn, Classical
- Previous heart transplant
- ECMO
- Previous mechanical support, specify
- Other, specify

Previous mechanical support, specify :*

Specify:*

Reason for admission:*

Current ICD device in place:*

- YES
- NO
- UNK

Events this hospitalization (Preimplant) (check all that apply):*

- Cardiac arrest
- Dialysis
- Intubation
- Major MI

- Cardiac surgery
- Positive blood cultures
- Other surgical procedures
- Major infections
- Unknown
- None

Infection type*

Location of infection:*

Other, specify:

IV inotrope therapy immediately prior to implant: YES NO UNK

- IV inotrope therapy agents (check all that apply):*
- Dobutamine
 - Dopamine
 - Milrinone
 - Levosimendan
 - Epinephrine
 - Norepinephrine
 - Isoproterenol
 - Other, specify
 - Unknown

Specify:

- Additional support interventions within 24 hours of implant (check all that apply):*
- IABP
 - Other VAD
 - Dialysis
 - Ultrafiltration
 - Ventilator
 - Feeding tube
 - ECMO
 - None

- Patient profile/status:*
- 1 "Critical Cardiogenic Shock": low BP unresponsive to support, compromised organ perfusion, < 24 hours survival expected without mechanical support
 - 1A "Critical Cardiogenic Shock": low BP unresponsive to support, compromised organ perfusion, < 24 hours survival expected without mechanical support Modifier A "Recurrent VT/VF"
 - 2 "Progressive Decline": not in imminent danger but worsening despite inotropic support, with

- declining renal function, nutrition, ambulation, other
- 2A "Progressive Decline": not in imminent danger but worsening despite inotropic support, with declining renal function, nutrition, ambulation, other Modifier A "Recurrent VT/VF"
- 3 "Stable but Inotrope dependent": unable to be weaned from inotropic support
- 3A "Stable but Inotrope dependent": unable to be weaned from inotropic support Modifier A "Recurrent VT/VF"
- 4 "Recurrent advanced heart failure": recurrent congestion despite good maintenance, needing repeated interventions beyond escalation of oral diuretics
- 4A "Recurrent advanced heart failure": recurrent congestion despite good maintenance, needing repeated interventions beyond escalation of oral diuretics Modifier A "Recurrent VT/VF"
- 5 "Exertion intolerant": comfortable at rest without obvious fluid overload but limited activities of daily living (ADL)
- 5A "Exertion intolerant": comfortable at rest without obvious fluid overload but limited activities of daily living (ADL) Modifier A "Recurrent VT/VF"
- 6 "Exertion limited": comfortable at rest and with ADL but meaningful activity limited
- 6A "Exertion limited": comfortable at rest and with ADL but meaningful activity limited Modifier A "Recurrent VT/VF"
- 7 "Advanced NYHA Class 3"

Co-morbidities

Diabetes:* YES NO UNK

Insulin-dependent:* YES NO UNK

Cardiac rhythm:*

Other, specify:*

COPD:*

Symptomatic peripheral vascular disease:* YES NO UNK

Connective tissue or inflammatory rheumatologic disease:* YES NO UNK

Hx of Hepatitis A:* YES NO UNK

Hx of Hepatitis B:* YES NO UNK

Hx of Hepatitis C:* YES NO UNK

Peripheral myopathy:* YES NO UNK

Definition: skeletal muscle biopsy abnormality or skeletal muscle weakness

Protein losing enteropathy:*

by physical exam.

YES NO UNK

Definition: Elevated alpha-1-antitrysin or iv albumin replacement for > 14 days.

Protein losing enteropathy (check all that apply):*

- Elevated alpha 1 antitrysin
- Albumin iv requirement
- Clinical diagnosis
- Unknown

Carotid artery disease:*

YES NO UNK

Definition: Having signs or symptoms of carotid artery disease or >50% narrowing of carotid.

History of neurological event:*

Cancer other than local skin cancer:*

YES NO UNK

Type of cancer:*

Other, specify:*

Any active treatment at time of implant for cancer other than local skin cancer:*

YES NO UNK

Smoking history:*

pack years:*

ST =

History of previous alcohol abuse:*

YES NO UNK

Current alcohol use:*

Drug abuse:*

Cardiac research trial - device (other than an MCS):*

YES NO UNK

Type of device:*

Cardiac research trial - drug:*

YES NO UNK

Type of drug:*

Transfusion history:*

YES NO UNK

General Hemodynamics

Heart rate:*

 beats per min

ST =

Systolic BP:*

 mm Hg

ST =

Diastolic BP:*

 mm Hg

ST =

Volume Status (peripheral edema):*

Ascites:*

YES NO UNK

ECG rhythm (cardiac rhythm):*
 Specify:*

Echo Hemodynamics

Were Echo Hemodynamics performed at pre-implant interval?* YES NO UNK

LVSF:* units ST=

Mitral regurgitation:*

Tricuspid regurgitation:*

Aortic regurgitation:*

LVEF:*

LVEDD:* cm ST=

RVEF:*

Swan Hemodynamics

Is swan in place at pre-implant interval?* YES NO UNK

Shunt Ratio (QpQs):* beats per min ST=

Pulmonary artery systolic pressure:* mm Hg ST=

Pulmonary artery diastolic pressure* mm Hg ST=

RA Pressure:* mm Hg ST=

Pulmonary artery wedge pressure:* mm Hg ST=

Cardiac output:* liters min ST=

Medications

Angiotensin receptor blocker drug:*

Amiodarone:*

ACE inhibitors:*

Beta-blockers:*

Aldosterone antagonist:*

Loop diuretics:*

Warfarin (coumadin):*

Anteplatelet therapy drug:*

Neseritide:* YES NO UNK

Nitric oxide:* YES NO UNK

- Outpatient (prior to admission) Inotrope Infusion (check all that apply)*
- None
 - Dopamine
 - Dobutamine
 - Milrinone
 - Isotroterenol
 - Epinephrine
 - Norepinephrine
 - Levosimendan
 - Unknown

Laboratory

Blood urea nitrogen:* mg/L ST=

Creatinine:* mg/dL ST=

Total bilirubin:* mg/dL ST=

Sodium:* mg/L ST=

INR:* international units ST=

White blood cell count:* K/uL ST=

Platelet:* K/uL ST=

SGOT/AST:* u/L ST=

SGPT/ALT:* u/L ST=

Cholesterol:* mg/dL ST=

CRP (C Reactive Protein):* mg/L ST=

Potassium:* mEq/L ST=

Hemoglobin:* mg/dL ST=

Protein C:* % ST=

Protein S:*	<input type="text"/> %	<input type="text"/> ST=
Anti-phospholipid (IgG):*	<input type="text"/> gplu/ml	<input type="text"/> ST=
Pre-albumin:*	<input type="text"/> mg/dL	<input type="text"/> ST=
Albumin:*	<input type="text"/> mg/dL	<input type="text"/> ST=
Brain natriuretic peptide BNP:*	<input type="text"/> pg/ml	<input type="text"/> ST=
NT pro brain natriuretic peptide Pro-BNP:*	<input type="text"/> pg/ml	<input type="text"/> ST=

Medical Condition

NYHA class:*

Ross classification fields are for patients < 6 yrs of age

Ross Classification of Congestive Heart Failure (patient < 6 yrs of age):*

Ross class II:*

- Mild tachypnea with feeds in infant
- Mild diaphoresis with feeds in infant
- Dyspnea on exercise in older children
- Unknown

Ross class III:*

- Marked tachypnea with exertion or with feeding
- Marked diaphoresis with exertion or with feeding
- Unknown

Ross class IV:*

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Exercise Function

6 minute walk:*	<input type="text"/> feet	ST=
VO2 Max:*	<input type="text"/> mL/min	ST=
R Value at peak:*	<input type="text"/> %	ST=

Quality of Life

Did the patient complete a EuroQol form: YES NO UNK

Displays when patient completed a EuroQol form

Mobility:*

Self care:*

Usual Activities (e.g. work, study, housework, family or leisure activities)*

Pain/discomfort:

Anxiety/depression:*

Your own health state today (0-100). 0=worst, 100=best:*

Have you experienced serious illness?* YES NO

Has your family experienced serious illness?* YES NO

Have you experienced serious illness in caring for others?* YES NO

Age in years:*

Sex:* Male Female

Are you:*

Do you now, or did you ever, work in health or social services:* YES NO

In what capacity:*

Which of the following best describes your main activity:*

Other, specify:*

What is the highest level of education you have completed:*

Zip code (if known):

Displays when patient did not complete a EuroQol form

Reason (as stated by patient) why the EUROqoL was not completed:*

Other, specify*

Reason (as stated by coordinator) why the EUROqoL was not completed:*

Other, specify*

Trailmaking Data

Status:*

Time:*

 sec



implant

Device Information

Additional indication for VAD:*

- Failure to wean from CPB
 Post Cardiac Surgery
 None

Enter cardiac operation:*

Device type:*

Device brand:*

Device brand (RVAD):*

Specify:*

Specify RVAD:*

Implant date:*

 mm/dd/yyyy

LVAD: device tracking number:*

ST=

LVAD: console tracking number:*

ST=

LVAD: cannulae location-inflow:*

LVAD: cannulae location-outflow:*

RVAD: device tracking number:*

ST=

RVAD: console tracking number:*

ST=

RVAD: cannulae location-inflow:*

TAH: device tracking number:*

ST=

TAH: console tracking number:*

ST=

Device Details

Concomitant surgery:*

- None
- ASD closure
- PFO closure
- RVAD implant
- ECMO decannulation
- CABG
- VSD closure
- Congenital cardiac surgery

- Valve Surgery: Aortic Repair
- Valve Surgery: Mitral Repair
- Valve Surgery: Tricuspid Repair
- Valve Surgery: Pulmonary Repair
- Valve Surgery: Aortic Replacement - Mechanical
- Valve Surgery: Aortic Replacement - Biological
- Valve Surgery: Mitral Replacement - Mechanical
- Valve Surgery: Mitral Replacement - Biological
- Valve Surgery: Tricuspid Replacement - Mechanical
- Valve Surgery: Tricuspid Replacement - Biological
- Valve Surgery: Pulmonary Replacement - Mechanical
- Valve Surgery: Pulmonary Replacement - Biological
- Other, specify

Specify*

CPB time:*

minutes

ST=

Time in OR for implant:*

minutes

ST=

Implant Discharge

Implant discharge date:* mm/dd/yyyy ST=

Patient discharged to:*

Acute care (ICU / CCU) duration of post-implant stay* days ST=

Intermediate/step-down care - duration of post-implant stay:* days ST=

Date of approximate discontinuation of inotropes:*

Intervention since implant:*

Type of surgical procedure:*

Type of non-surgical procedure:*

Other cardiac surgical procedure:*

Other procedure:*

Enter type of procedure:*

Enter procedure:*

General Hemodynamics

Heart rate:* beats per min ST=

Systolic BP:* mm Hg ST=

Diastolic BP:* mm Hg ST=

Volume Status (peripheral edema):*

Ascites:* YES NO UNK

ECG rhythm (cardiac rhythm):*

Specify:*

Height:* in cm ST=

Weight:* lbs kg ST=

Medications

Currently on Inotrope therapy?* YES NO UNK

List drug:* Dopamine Dobutamine

- Milrinone
- Isoproterenol
- Epinephrine
- Norepinephrine
- Levosimendan
- Unknown

Nesiritide:* YES NO UNK

Angiotensin receptor blocker drug:* YES NO UNK

Amiodarone:* YES NO UNK

ACE inhibitors:* YES NO UNK

Beta-blockers:* YES NO UNK

Aldosterone antagonist:* YES NO UNK

Loop Diuretics:* YES NO UNK

Warfarin (coumadin):* YES NO UNK

Anteplatelet therapy drug:* YES NO UNK

Select drug(s)*

- Aspirin
- Dexpan
- Dipyridamole
- Clopidogrel
- Ticlopidine
- Unknown
- Other, specify

Specify:*

Nitric oxide:* YES NO UNK

Laboratory

Blood urea nitrogen:* mg/L ST=

Creatinine:* mg/dL ST=

Total bilirubin:* mg/dL ST=

Bilirubin direct:* mg/dL ST=

Bilirubin indirect:* ST=

Sodium:*	<input type="text"/> mg/dL	<input type="text"/>
	<input type="text"/> mg/L	ST= <input type="text"/>
INR:*	<input type="text"/> international units	ST= <input type="text"/>
White blood cell count:*	<input type="text"/> K/uL	ST= <input type="text"/>
Platelet:*	<input type="text"/> K/uL	ST= <input type="text"/>
SGOT/AST:*	<input type="text"/> u/L	ST= <input type="text"/>
SGPT/ALT:*	<input type="text"/> u/L	ST= <input type="text"/>
Cholesterol:*	<input type="text"/> mg/dL	ST= <input type="text"/>
CRP (C Reactive Protein):*	<input type="text"/> mg/L	ST= <input type="text"/>
Potassium:*	<input type="text"/> mEq/L	ST= <input type="text"/>
Hemoglobin:*	<input type="text"/> mg/dL	ST= <input type="text"/>
Plasma-free hemoglobin:*	<input type="text"/> mg/dL	ST= <input type="text"/>
Reticulocyte count:*	<input type="text"/> %	ST= <input type="text"/>
Positive antiheparin/platelet antibody (HIT):*	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> UNK	
Is Patient on Direct Thrombin Inhibitors?*	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> UNK	
Enter drugs: (check all that apply)*	<input type="checkbox"/> Aspirin	
	<input type="checkbox"/> Dipyridamole	
	<input type="checkbox"/> Plavix	
	<input type="checkbox"/> Heparin	
	<input type="checkbox"/> Coumadin	
	<input type="checkbox"/> Direct thrombin inhibitors (ex: arg, lip, val?)	
LDH:*	<input type="text"/> U/L	ST= <input type="text"/>
TEG profile, MA k:*	<input type="text"/> max amplitude in kaolin	ST= <input type="text"/>
TEG profile, R k:*	<input type="text"/> reaction time in kaolin	ST= <input type="text"/>
TEG profile, R h:*	<input type="text"/> reaction time w/heparinase	ST= <input type="text"/>
Protein C:*	<input type="text"/> %	ST= <input type="text"/>

Protein S:*	<input type="text"/> %	<input type="text"/>
		ST=
Anti-phospholipid (IgG):*	<input type="text"/> gplu/ml	<input type="text"/>
		ST=
Pre-albumin:*	<input type="text"/> mg/dL	<input type="text"/>
		ST=
Albumin:*	<input type="text"/> mg/dL	<input type="text"/>
		ST=
Brain natriuretic peptide BNP:*	<input type="text"/> pg/ml	<input type="text"/>
		ST=
NT pro brain natriuretic peptide Pro-BNP:*	<input type="text"/> pg/ml	<input type="text"/>
		ST=

Device Parameters

LVAD device type:*	<input type="text"/>
RVAD device type:*	<input type="text"/>

LVAD Device Parameters (pulsatile)

LVAD flow:*	<input type="text"/> L/min	ST = <input type="text"/>
LVAD - pump drive pressure (pneumatic devices only):*	<input type="text"/> mmHg	ST = <input type="text"/>
LVAD - Select Control Mode:*	<input type="text"/>	
LVAD - Fixed - enter rate:*	<input type="text"/>	ST = <input type="text"/>

LVAD Device Parameters (rotary)

LVAD flow:*	<input type="text"/> L/min	ST = <input type="text"/>
LVAD pump speed:*	<input type="text"/> rpm	ST = <input type="text"/>
LVAD power (watts):*	<input type="text"/> watts	ST = <input type="text"/>
LVAD current (amps):*	<input type="text"/> amps	ST = <input type="text"/>

RVAD Device Parameters (pulsatile)

RVAD flow:*	<input type="text"/> L/min	ST = <input type="text"/>
RVAD - pump drive pressure (pneumatic devices only):*	<input type="text"/> mmHg	ST = <input type="text"/>
RVAD - Select Control Mode:*	<input type="text"/>	
RVAD - Fixed - enter rate:*	<input type="text"/>	ST = <input type="text"/>

RVAD Device Parameters (rotary)

RVAD flow:*	<input type="text"/>	L/min	ST =	<input type="text"/>
RVAD pump speed:*	<input type="text"/>	rpm	ST =	<input type="text"/>
RVAD power (watts):*	<input type="text"/>	watts	ST =	<input type="text"/>
RVAD current (amps):*	<input type="text"/>	amps	ST =	<input type="text"/>

Adverse Event Reminders Appendix A: Adverse Event Definitions

Major Bleeding

Did Patient (if >= 50 kg) require >= 2 units or (if < 50 kg) require >= 10 cc/kg of packed red blood cells (p.c.) in any 24 period since last INTERMACS report/last followup?*

YES NO UNK

Date patient received p.c.:* mm/dd/yyyy ST=

Approximate # of units p.c. received:*

- Anticoagulant therapy at time of event (check all that apply):*
- Warfarin
 - Heparin
 - Lovenox
 - Aspirin
 - Dipyridamole
 - Clopidogrel (plavix)
 - Argatroban
 - Bilvalirudin
 - Fondaparinux
 - Hirudin
 - Lepirudin
 - Ximelagatran
 - None
 - Other

Specify:*

Cardiac Arrhythmia

Did a documented

arrhythmia result in clinical compromise since last INTERMACS report/last followup?*

- YES NO UNK

Event Date:* mm/dd/yyyy

ST=

Type of cardiac arrhythmia:*

Pericardial Fluid Collection

Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?:*

- YES NO UNK

Event date..* mm/dd/yyyy

ST=

Signs of tamponade:*

- YES NO UNK

Method of drainage:*

- OP Cath Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup?:*

- YES NO UNK

Plasma-free hemoglobin measurement:* mg/dL

ST=

Hematocrit measurement:* %

ST=

Patient has Hyperbilirubinemia (Total Bilirubin > 2 mg/dl):*

- YES NO UNK

Cause of Hemolysis:*

Other, specify:*

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:*

- YES NO UNK

Total bilirubin measurement:* mg/dL

ST=

SGOT/AST measurement:* u/L

ST=

SGPT/ALT measurement:* u/L

ST=

Hypertension

Did onset bp \geq 140mm Hg systolic or 90mm Hg diastolic (Pediatric patient: $>$ 95th percentile, see definition) occur since last INTERMACS report/last followup?:*

YES NO UNK

Systolic bp:* mm Hg

ST=

Diastolic bp:* mm Hg

ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup/admission?:*

YES NO UNK

Date of event:* mm/dd/yyyy

ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:*

YES NO UNK

Renal Dysfunction

Did renal dysfunction requiring dialysis occur since last INTERMACS report/last followup?:*

YES NO UNK

Event date.:* mm/dd/yyyy

ST=

Dialysis duration:* weeks

ST=

Peak creatinine measurement:* mg/dL

ST=

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:*

YES NO UNK

Date of event:* mm/dd/yyyy

ST=

Intubation duration:* days

ST=

Was a tracheotomy performed?:* YES NO UNK

Right Heart Failure

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:*

- YES NO UNK

Event date.:* mm/dd/yyyy

ST=

Check all signs/symptoms that apply:*

- CVP > 18 mmHg
 CI < 2.0 L/min/M2
 Ascites
 Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?*

- YES NO UNK

Date.:* mm/dd/yyyy

ST=

Location:.*

Other acute perfusion deficit:.*

Confirmation source:.*

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
 Heparin
 Lovenox
 Aspirin
 Dipyridamole
 Clopidogrel (plavix)
 Argatroban
 Bilvalirudin
 Fondaparinux
 Hirudin
 Lepirudin
 Ximelagatran
 None
 Other

Specify:.*

Venous Thromboembolism Event

Evidence of Venous

Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- Deep Vein thrombosis
- Pulmonary Embolis
- Other, specify
- Unknown
- None

Specify event:*

Enter deep vein thrombosis date:*

mm/dd/yyyy

ST=

Enter pulmonary embolis date:*

mm/dd/yyyy

ST=

Enter other date:*

mm/dd/yyyy

ST=

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup?*

- YES
- NO
- UNK

Date:*

mm/dd/yyyy

ST=

Other

Other Major Serious Adverse Event since last INTERMACS report/last followup:

Adverse Events

Was there a major infection?*

YES NO UNK

Date of onset:*

mm/dd/yyyy

ST=

Location of infection:
(check all that apply)*

- Pump / related - Drive Line
- Pump / related - Pump Pocket
- Pump / related - Pump Interior
- Positive Blood cultures
- Line Sepsis
- Pulmonary
- Urinary Tract
- Mediastinum
- Peripheral Wound
- GI
- Unknown
- Other, specify

Specify:

Type of infection:*

Causative or contributing factors to the infection AE:
(check all that apply)*

- Patient condition
- Patient non-compliance with Medications
- Patient non-compliance with Device Maintenance
- Patient non-compliance with Followup Visits
- Device related
- Complexities of Medical Management
- Unknown

Intervention:*

Infection contribute to Death:*

YES NO UNK

Was there a neurological dysfunction?*

YES NO UNK

Date of onset:*

mm/dd/yyyy

ST=

Neurological dysfunction categories:*

Other, specify:*

Causative or contributing factors to the neurological dysfunction AE (check all that apply):*

- Patient not taking anticoagulation medication properly
- If patient receiving warfarin then, evidence of INR above target range
- If patient receiving warfarin then, evidence of INR below target range
- If patient receiving heparin then, evidence of INR above target range
- If patient receiving heparin then, evidence of INR below target range
- Complexities of Medical Management
- Unknown

Details of CNS event:*

Other, specify:*

Location of CNS event:*

Other, specify:*

Method of diagnosis of CNS event:*

Other, specify:*

Description of clinical event:*

Stroke severity:*

Other, specify:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

Specify:*

Surgical intervention:*

- YES
- NO
- UNK

Drug intervention:*

- YES
- NO
- UNK

Treatment:*

- Heparin

- Thrombolytics
- Anti-Seizure
- None of the above

Did this Neurological Dysfunction Adverse Event contribute to the patient's death:*

- YES
- NO
- UNK

Was there a device malfunction?*

- YES
- NO
- UNK

Date of onset:*

mm/dd/yyyy

ST=

Major pump unit involved (check all that apply):*

- Blood Pump
- Drive Unit Failure
- External Control System Failure
- Device Thrombosis

Blood Pump Specify:*

Drive Unit Failure Specify:*

External Control System Failure Specify:*

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

- External Battery Malfunction
- Internal Battery Malfunction
- External Controller Malfunction
- Internal Controller Malfunction
- Driveline Malfunction
- Inflow Graft Malfunction/Malposition
- Outflow Graft Malfunction/Malposition
- Pump Drive Unit Malfunction
- TET System Malfunction
- Inflow Valve
- Outflow Valve
- Volume Compensator Malfunction
- Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

- Patient noncompliance in device maintenance and protection
- Patient error in caring for system
- Inadequate instructions from caregivers
- No specific contributing cause identified

Device malfunction intervention (check all that apply):*

- Replacement of Internal Battery
- Replacement of External Battery
- Replacement of External Controller
- Replacement of Internal Controller
- Replacement of Driveline
- Replacement of Inflow Graft
- Replacement of Outflow Graft
- Replacement of Pump
- Replacement of TET System
- Replacement of Pump Valve
- Replacement of Volume Compensator
- Replacement of Other Component, specify
- Switch from Vented Electric to Pneumatic-mode
- Other Interventions, specify
- None
- Unknown

Specify component:*

Specify:*

Surgical procedure required:*

- YES
- NO
- UNK

Device explanted:*

YES NO UNK

Device malfunction adverse event cause patient's death:*

YES NO UNK

Death

Is the patient deceased?*

YES NO

Death date:*

mm/dd/yyyy

ST=

Was device functioning normally?:*

YES NO UNK

Was there an operation associated with device malfunction?:*

YES NO UNK

Post mortem device explant:*

YES NO UNK

Did device go to manufacturer:*

YES NO UNK

Timing of death:*

Expected Unexpected Unknown

Autopsy: *

YES NO UNK

Primary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Explant

Was the device explanted/patient transplanted?*

YES NO

Device explanted:*

Explant date:*

mm/dd/yyyy

ST=

Explant reason:*

Other, specify:*

Transplant date:*

mm/dd/yyyy

ST=

Waitlist ID:*

1 Month Post-Implant (Fields for 1 week and 1 month post-implant)

Is patient still in hospital at 1 month (+/- 7 days) from implant surgery?:* YES NO UNK

Post-Implant Date:* mm/dd/yyyy

General Hemodynamics

Heart rate:* beats per min ST=

Systolic BP:* mm Hg ST=

Diastolic BP:* mm Hg ST=

Volume Status (peripheral edema):*

Ascites:* YES NO UNK

ECG rhythm (cardiac rhythm):*

Specify:*

Height:* in cm ST=

Weight:* lbs kg ST=

Echo Hemodynamics

Were Echo Hemodynamics performed at reporting interval?* YES NO UNK

Swan Hemodynamics

Is swan in place at reporting interval?* YES NO UNK

Medications

Currently on Inotrope therapy?* YES NO UNK

Nesitiride:* YES NO UNK

Angiotensin receptor blocker drug:* YES NO UNK

Amiodarone:* YES NO UNK

ACE inhibitors:* YES NO UNK

Beta-blockers:* YES NO UNK

Aldosterone antagonist:* YES NO UNK

Loop Diuretics:*

YES NO UNK

Warfarin (coumadin):*

YES NO UNK

Antiplatelet therapy drug:*

YES NO UNK

Nitric oxide:*

YES NO UNK

Laboratory

Blood urea nitrogen:*

mg/L

ST=

Creatinine:*

mg/dL

ST=

Total bilirubin:*

mg/dL

ST=

Bilirubin direct:*

mg/dL

ST=

Bilirubin indirect:*

mg/dL

ST=

Sodium:*

mg/L

ST=

INR:*

international units

ST=

White blood cell count:*

K/uL

ST=

Platelet:*

K/uL

ST=

SGOT/AST:*

u/L

ST=

SGPT/ALT:*

u/L

ST=

Cholesterol:*

mg/dL

ST=

CRP (C Reactive Protein):*

mg/L

ST=

Potassium:*

mEq/L

ST=

Hemoglobin:*

mg/dL

ST=

Plasma-free hemoglobin:*

mg/dL

ST=

Reticulocyte count:*

%

ST=

Positive antiheparin/platelet antibody (HIT):*

YES NO UNK

Is Patient on Direct Thrombin Inhibitors?*

YES NO UNK

LDH:*	<input type="text"/> U/L	ST=	<input type="text"/>
TEG profile, MA k:*	<input type="text"/> max amplitude in kaolin	ST=	<input type="text"/>
TEG profile, R k:*	<input type="text"/> reaction time in kaolin	ST=	<input type="text"/>
TEG profile, R h:*	<input type="text"/> reaction time w/heparinase	ST=	<input type="text"/>
Protein C:*	<input type="text"/> %	ST=	<input type="text"/>
Protein S:*	<input type="text"/> %	ST=	<input type="text"/>
Anti-phospholipid (IgG):*	<input type="text"/> gplu/ml	ST=	<input type="text"/>
Pre-albumin:*	<input type="text"/> mg/dL	ST=	<input type="text"/>
Albumin:*	<input type="text"/> mg/dL	ST=	<input type="text"/>
Brain natriuretic peptide BNP:*	<input type="text"/> pg/ml	ST=	<input type="text"/>
NT pro brain natriuretic peptide Pro-BNP:*	<input type="text"/> pg/ml	ST=	<input type="text"/>

Medical Condition

NYHA class:*

Ross classification fields are for patients < 6 yrs of age

Ross Classification of Congestive Heart Failure (patient < 6 yrs of age):*

Ross class II:*

- Mild tachypnea with feeds in infant
- Mild diaphoresis with feeds in infant
- Dyspnea on exercise in older children
- Unknown

Ross class III:*

- Marked tachypnea with exertion or with feeding
- Marked diaphoresis with exertion or with feeding
- Unknown

Ross class IV:*

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Has patient been rehospitalized since implant hospitalization?* YES NO UNK

Adverse Event Reminders Appendix A: Adverse Event Definitions

Major Bleeding

Did Patient (if >= 50 kg) require >= 2 units or (if < 50 kg) require >= 10 cc/kg of packed red blood cells (p.c.) in any 24 period since last INTERMACS report/last followup?*

YES NO UNK

Date patient received p.c.:* mm/dd/yyyy

ST=

Approximate # of units p.c. received:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise since followup/admission?*

YES NO UNK

Event Date:* mm/dd/yyyy

ST=

Type of cardiac arrhythmia:*

Pericardial Fluid Collection

Did a pericardial effusion that required drainage YES NO UNK

occur since last INTERMACS report/last followup?:*

Event date:.* mm/dd/yyyy

ST=

Signs of tamponade:.* YES NO UNK

Method of drainage:.* OP Cath Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup?:* YES NO UNK

Plasma-free hemoglobin measurement:.* mg/dL

ST=

Hematocrit measurement:.* %

ST=

Patient has Hyperbilirubinemia (Total Bilirubin > 2 mg/dl):.* YES NO UNK

Cause of Hemolysis:.*

Other, specify:.*

Hepatic Dysfunction (Not included with 1 week post-implant)

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:* YES NO UNK

Total bilirubin measurement:.* mg/dL

ST=

SGOT/AST measurement:.* u/L

ST=

SGPT/ALT measurement:.* u/L

ST=

Hypertension

Did onset bp >= 140mm Hg systolic or 90mm Hg diastolic (Pediatric patient: > 95th percentile, see definition) occur since last INTERMACS report/last followup?:* YES NO UNK

Systolic bp:.* mm Hg

ST=

Diastolic bp:.* mm Hg

ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup?:* YES NO UNK

Date of event:.* mm/dd/yyyy

ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:* YES NO UNK

Renal Dysfunction

Did renal dysfunction requiring dialysis occur since last INTERMACS report/last followup?:* YES NO UNK

Event date:.* mm/dd/yyyy

ST=

Dialysis duration:.* weeks

ST=

Peak creatinine measurement:.* mg/dL

ST=

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:* YES NO UNK

Date of event:.* mm/dd/yyyy

ST=

Intubation duration:.* days

ST=

Was a tracheotomy performed?:* YES NO UNK

Right Heart Failure (Not included with 1 week post-implant)

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:* YES NO UNK

Event date:.* mm/dd/yyyy

ST=

Check all signs/symptoms that apply:.* CVP > 18 mmHg
 CI < 2.0 L/min/M2

- Ascites
- Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?*

- YES
- NO
- UNK

Date:* mm/dd/yyyy

ST=

Location:*

Other acute perfusion deficit:*

Confirmation source:*

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- Deep Vein thrombosis
- Pulmonary Embolis
- Other, specify
- Unknown
- None

Specify event:*

Enter deep vein thrombosis date:* mm/dd/yyyy

ST=

Enter pulmonary embolis date:*

mm/dd/yyyy

ST=

Enter other date:*

mm/dd/yyyy

ST=

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify: *

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup?*

- YES
- NO
- UNK

Date:*

mm/dd/yyyy

ST=

Other

Other Major Serious Adverse Event since last INTERMACS report/last followup:

Adverse Events

Was there a major infection?*

- YES
- NO
- UNK

Date of onset:*

mm/dd/yyyy

ST=

Location of infection: (check all that apply)*

- Pump / related - Drive Line

- Pump / related - Pump Pocket
- Pump / related - Pump Interior
- Positive Blood cultures
- Line Sepsis
- Pulmonary
- Urinary Tract
- Mediastinum
- Peripheral Wound
- GI
- Unknown
- Other, specify

Specify:*

Type of infection:*

Causative or contributing factors to the infection AE: (check all that apply)*

- Patient condition
- Patient non-compliance with Medications
- Patient non-compliance with Device Maintenance
- Patient non-compliance with Followup Visits
- Device related
- Complexities of Medical Management
- Unknown

Intervention:*

Infection contribute to Death:*

- YES
- NO
- UNK

Was there a neurological dysfunction?*

- YES
- NO
- UNK

Date of onset:*

mm/dd/yyyy

ST=

Neurological dysfunction categories:*

Other, specify:*

Causative or contributing factors to the neurological dysfunction AE (check all that apply):*

- Patient not taking anticoagulation medication properly
- If patient receiving warfarin then, evidence of INR above target range
- If patient receiving warfarin then, evidence of INR below target range
- If patient receiving heparin then, evidence of INR above target range
- If patient receiving heparin then, evidence of INR below target range
- Complexities of Medical Management

Unknown

Details of CNS event:*

Other, specify:*

Location of CNS event:*

Other, specify:*

Method of diagnosis of CNS event:*

Other, specify:*

Description of clinical event:*

Stroke severity:*

Other, specify:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

Specify:*

Surgical intervention:*

- YES
- NO
- UNK

Drug intervention:*

- YES
- NO
- UNK

Treatment:*

- Heparin
- Thrombolytics
- Anti-Seizure
- None of the above

Did this Neurological Dysfunction Adverse Event contribute to the patient's death:*

- YES
- NO
- UNK

Was there a device malfunction?*

- YES
- NO
-

UNK

Date of onset:*

mm/dd/yyyy

ST=

Major pump unit involved (check all that apply):*

- Blood Pump
- Drive Unit Failure
- External Control System Failure
- Device Thrombosis

Blood Pump Specify:*

Drive Unit Failure Specify:*

External Control System Failure Specify:*

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

- External Battery Malfunction
- Internal Battery Malfunction
- External Controller Malfunction
- Internal Controller Malfunction
- Driveline Malfunction
- Inflow Graft Malfunction/Malposition
- Outflow Graft Malfunction/Malposition
- Pump Drive Unit Malfunction
- TET System Malfunction
- Inflow Valve
- Outflow Valve
- Volume Compensator Malfunction
- Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Other, specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

- Patient noncompliance in device maintenance and protection
- Patient error in caring for system
- Inadequate instructions from caregivers
- No specific contributing cause identified

Device malfunction intervention (check all that apply):*

- Replacement of Internal Battery
- Replacement of External Battery
- Replacement of External Controller
- Replacement of Internal Controller
- Replacement of Driveline
- Replacement of Inflow Graft
- Replacement of Outflow Graft
- Replacement of Pump
- Replacement of TET System
- Replacement of Pump Valve
- Replacement of Volume Compensator
- Replacement of Other Component, specify
- Switch from Vented Electric to Pneumatic-mode
- Other Interventions, specify
- None
- Unknown

Specify component:*

Other, specify:*

Surgical procedure required:*

- YES
- NO
- UNK

Device explanted:*

- YES
- NO
- UNK

Device malfunction adverse event cause patient's death:*

- YES
- NO
- UNK

Death

Is the patient deceased?*

- YES
- NO

Death date:*

mm/dd/yyyy

ST=

Was device functioning normally?:* YES NO UNK

Was there an operation associated with device malfunction?:* YES NO UNK

Post mortem device explant?:* YES NO UNK

Did device go to manufacturer?:* YES NO UNK

Timing of death:* Expected Unexpected Unknown

Autopsy: * YES NO UNK

Primary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Explant

Was the device explanted/patient transplanted?* YES NO

Device explanted:*

Explant date:* mm/dd/yyyy

ST=

Explant reason:*

Other, specify:*

Transplant date:* mm/dd/yyyy

ST=

Waitlist ID:*

3 Month Follow-Up (Fields are for 3 month and 6 month follow-ups)

Was patient seen in the hospital or clinic at follow-up time period (+/- 1 month at 3 month followup)?* YES NO UNK

Follow-up date:* mm/dd/yyyy

General Hemodynamics

Heart rate:* beats per min ST=

Systolic BP:* mm Hg ST=

Diastolic BP:* mm Hg ST=

Volume Status (peripheral edema):*

Ascites:* YES NO UNK

ECG rhythm (cardiac rhythm):*

Specify:*

Height:* in cm ST=

Weight:* lbs kg ST=

Echo Hemodynamics

Were Echo Hemodynamics performed at follow-up interval?* YES NO UNK

LVSF:* units ST=

Mitral regurgitation:*

Tricuspid regurgitation:*

Aortic regurgitation:*

LVEF:*

LVEDD:* cm ST=

RVEF:*

Swan Hemodynamics

Is swan in place at follow-up interval?* YES NO UNK

Shunt Ratio (QpQs):* beats per min ST=

Pulmonary artery systolic pressure:* mm Hg ST=

Pulmonary artery diastolic pressure* mm Hg

ST=

RA Pressure:* mm Hg

ST=

Pulmonary artery wedge pressure:* mm Hg

ST=

Cardiac output:* liters min

ST=

Medications

Currently on Inotrope therapy?* YES NO UNK

List drug:*

- Dopamine
- Dobutamine
- Milrinone
- Isoproterenol
- Epinephrine
- Norepinephrine
- Levosimendan
- Unknown

Nesitiride:* YES NO UNK

Angiotensin receptor blocker drug:* YES NO UNK

Amiodarone:* YES NO UNK

ACE inhibitors:* YES NO UNK

Beta-blockers:* YES NO UNK

Aldosterone antagonist:* YES NO UNK

Loop Diuretics:* YES NO UNK

Warfarin (coumadin):* YES NO UNK

Anteplatelet therapy drug:* YES NO UNK

Select drug(s)*

- Aspirin
- Dextran
- Dipyridamole
- Clopidogrel
- Ticlopidine

Unknown

Other, specify

Specify:*

Nitric oxide:*

YES NO UNK

Laboratory

Blood urea nitrogen:* mg/L ST=

Creatinine:* mg/dL ST=

Total bilirubin:* mg/dL ST=

Bilirubin direct:* mg/dL ST=

Bilirubin indirect:* mg/dL ST=

Sodium:* mg/L ST=

INR:* international units ST=

White blood cell count:* K/uL ST=

Platelet:* K/uL ST=

SGOT/AST:* u/L ST=

SGPT/ALT:* u/L ST=

Cholesterol:* mg/dL ST=

CRP (C Reactive Protein):* mg/L ST=

Potassium:* mEq/L ST=

Hemoglobin:* mg/dL ST=

Plasma-free hemoglobin:* mg/dL ST=

Reticulocyte count:* % ST=

Positive antiheparin/platelet antibody (HIT):* YES NO UNK

Is Patient on Direct Thrombin Inhibitors?* YES NO UNK

Enter drugs:
(check all that apply)*

- Aspirin
- Dipyridamole
- Plavix
- Heparin
- Coumadin
- Direct thrombin inhibitors (ex: arg, lip, val?)

LDH:*	<input type="text"/> U/L	ST=	<input type="text"/>
TEG profile, MA k:*	<input type="text"/> max amplitude in kaolin	ST=	<input type="text"/>
TEG profile, R k:*	<input type="text"/> reaction time in kaolin	ST=	<input type="text"/>
TEG profile, R h:*	<input type="text"/> reaction time w/heparinase	ST=	<input type="text"/>
Protein C:*	<input type="text"/> %	ST=	<input type="text"/>
Protein S:*	<input type="text"/> %	ST=	<input type="text"/>
Anti-phospholipid (IgG):*	<input type="text"/> gplu/ml	ST=	<input type="text"/>
Pre-albumin:*	<input type="text"/> mg/dL	ST=	<input type="text"/>
Albumin:*	<input type="text"/> mg/dL	ST=	<input type="text"/>
Brain natriuretic peptide BNP:*	<input type="text"/> pg/ml	ST=	<input type="text"/>
NT pro brain natriuretic peptide Pro-BNP:*	<input type="text"/> pg/ml	ST=	<input type="text"/>

Device Parameters

LVAD device type:*	<input type="text"/>
RVAD device type:*	<input type="text"/>

LVAD Device Parameters (pulsatile)

LVAD flow:*	<input type="text"/> L/min	ST =	<input type="text"/>
LVAD - pump drive pressure (pneumatic devices only):*	<input type="text"/> mmHg	ST =	<input type="text"/>
LVAD - Select Control Mode:*	<input type="text"/>		
LVAD - Fixed - enter rate:*	<input type="text"/>	ST =	<input type="text"/>

LVAD Device Parameters (rotary)

LVAD flow:* L/min ST =

LVAD pump speed:* rpm ST =

LVAD power (watts):* watts ST =

LVAD current (amps):* amps ST =

RVAD Device Parameters (pulsatile)

RVAD flow:* L/min ST =

RVAD - pump drive pressure (pneumatic devices only):* mmHg ST =

RVAD - Select Control Mode:*

RVAD - Fixed - enter rate:* ST =

RVAD Device Parameters (rotary)

RVAD flow:* L/min ST =

RVAD pump speed:* rpm ST =

RVAD power (watts):* watts ST =

RVAD current (amps):* amps ST =

Exercise Function

6 minute walk:* feet ST=

VO2 Max:* mL/min ST=

R Value at peak:* % ST=

Medical Condition

NYHA class:*

Ross classification fields are for patients < 6 yrs of age

Ross Classification of Congestive Heart Failure (patient < 6 yrs of age):*

- Ross class II:*
- Mild tachypnea with feeds in infant
 - Mild diaphoresis with feeds in infant

- Ross class III:*
- Dyspnea on exercise in older children
 - Unknown
 - Marked tachypnea with exertion or with feeding
 - Marked diaphoresis with exertion or with feeding
 - Unknown

- Ross class IV:*
- Tachypnea
 - Retractions
 - Grunting
 - Diaphoresis
 - Unknown

Has patient been rehospitalized since implant hospitalization?*

YES NO UNK

Patient Status

Current device strategy:*

Other, specify:*

- Check all that apply:*
- Advanced age
 - Fixed pulmonary hypertension
 - Patient refuses transplant
 - Contraindication to immunotherapy
 - Frailty
 - Malnutrition/cachexia
 - Large BMI
 - Musculoskeletal limitations
 - History of solid organ cancer
 - History of lymphoma, leukemia
 - Major stroke
 - Renal dysfunction
 - Pulmonary disease
 - Severe diabetes
 - Peripheral vascular disease
 - Other comorbidity
 - Risk of recurrent infection
 - Pulmonary hypertension
 - Recent pulmonary embolus

- All sensitization
- Heparin-induced thrombocytopenia
- Current infection
- Limited cognition/understanding
- Limited social support
- Illicit drug use
- Alcohol abuse
- Still smoking
- Severe depression
- Other major psychiatric diagnosis
- Repeated non-compliance
- Multiple sternotomies
- Mediastinal radiation
- Thoracic aortic disease
- Other, specify
- None

Other, specify:

Adverse Event Reminders Appendix A: Adverse Event Definitions

Major Bleeding

Did Patient (if >= 50 kg) require >= 2 units or (if < 50 kg) require >= 10 cc/kg of packed red blood cells (p.c.) in any 24 period since last INTERMACS report/last followup?*

- YES NO UNK

Date patient received mm/dd/yyyy

ST=

Did the patient require hospitalization:*

- YES NO UNK

Approximate # of units p.c. received:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)

- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise since followup/admission?*

- YES NO UNK

Event Date: * mm/dd/yyyy

ST=

Type of cardiac arrhythmia: *

Pericardial Fluid Collection

Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?*

- YES NO UNK

Event date.: * mm/dd/yyyy

ST=

Signs of tamponade: *

- YES NO UNK

Method of drainage: *

- OP Cath Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup?*

- YES NO UNK

Plasma-free hemoglobin measurement: * mg/dL

ST=

Hematocrit measurement: * %

ST=

Patient has Hyperbilirubinemia (Total Bilirubin > 2 mg/dl): *

- YES NO UNK

Cause of Hemolysis: *

Other, specify: *

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:* YES NO UNK

Total bilirubin measurement:* mg/dL ST=

SGOT/AST measurement:* u/L ST=

SGPT/ALT measurement:* u/L ST=

Hypertension

Did onset bp >= 140mm Hg systolic or 90mm Hg diastolic (Pediatric patient: > 95th percentile, see definition) occur since last INTERMACS report/last followup?:* YES NO UNK

Systolic bp:* mm Hg ST=

Diastolic bp:* mm Hg ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup?:* YES NO UNK

Date of event:* mm/dd/yyyy ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:* YES NO UNK

Renal Dysfunction

Did renal dysfunction requiring dialysis occur since last INTERMACS report/last followup?:* YES NO UNK

Event date.:* mm/dd/yyyy ST=

Dialysis duration:* weeks ST=

Peak creatinine mg/dL ST=

measurement:*

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:*

YES NO UNK

Date of event:*

 mm/dd/yyyy

ST=

Intubation duration:*

 days

ST=

Was a tracheotomy performed?:*

YES NO UNK

Right Heart Failure

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:*

YES NO UNK

Event date.:*

 mm/dd/yyyy

ST=

Check all signs/symptoms that apply:*

- CVP > 18 mmHg
- CI < 2.0 L/min/M2
- Ascites
- Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?*

YES NO UNK

Date:*

 mm/dd/yyyy

ST=

Location:*

Other acute perfusion deficit:*

Confirmation source:*

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)

- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- Deep Vein thrombosis
- Pulmonary Embolis
- Other, specify
- Unknown
- None

Specify event:*

Enter deep vein thrombosis date:*

mm/dd/yyyy

ST=

Enter pulmonary embolis date:*

mm/dd/yyyy

ST=

Enter other date:*

mm/dd/yyyy

ST=

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None

Other

Specify:

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup?*

YES NO UNK

Date: mm/dd/yyyy

ST=

Other

Other Major Serious Adverse Event since last INTERMACS report/last followup:

Rehospitalization

Was there an occurrence of rehospitalization?*

YES NO

Date of admission: mm/dd/yyyy

ST=

Discharge associated with this hospitalization* mm/dd/yyyy

ST=

Reason for admission (check all that apply):*

- Cardiac Arrhythmia
- Bleeding
- Cardiac Tamponade
- Hematoma
- Hemolysis
- Hepatic Dysfunction
- Hypertension
- Infection
- GI Disorder
- Pulmonary Disorder
- Limb vascular complication
- Pulmonary Embolism/Hemorrhage
- Planned Procedure, specify
- Device Malfunction
- Myocardial Infarction
- Neurological Dysfunction
- Psychiatric Episode

- Renal Dysfunction
- Right Heart Failure
- Non-CNS Thromboembolic (TE) Event
- Wound Complication
- Unknown
- Other, specify

Procedure:*

Specify:*

Rehospitalization intervention:*

Type of surgical procedure:*

Type of procedure:(non cardiac surgical procedure)*

Type of other cardiac procedure:*

Specify:*

Type of cardiac procedure:*

Other procedure:*

Specify:*

Enter CVP:* mm/Hg ST=

Enter PA systolic pressure:* mm/Hg ST=

Enter PA diastolic pressure:* mm/Hg ST=

Enter PCW pressure:* mm/Hg ST=

Enter cardiac output:* L/min ST=

Adverse Events

Was there a major infection?*

YES NO UNK

Date of onset:* mm/dd/yyyy

ST=

Location of patient:* In hospital Out of hospital Unknown

- Location of infection: (check all that apply)*
- Pump / related - Drive Line
 - Pump / related - Pump Pocket
 - Pump / related - Pump Interior
 - Positive Blood cultures
 - Line Sepsis
 - Pulmonary
 - Urinary Tract

- Mediastinum
- Peripheral Wound
- GI
- Unknown
- Other, specify

Specify:*

Type of infection:*

Causative or contributing factors to the infection AE: (check all that apply)*

- Patient condition
- Patient non-compliance with Medications
- Patient non-compliance with Device Maintenance
- Patient non-compliance with Followup Visits
- Device related
- Complexities of Medical Management
- Unknown

Intervention:*

Infection contribute to Death:*

- YES
- NO
- UNK

Was there a neurological dysfunction?*

- YES
- NO
- UNK

Date of onset:*

mm/dd/yyyy

ST=

Location of patient:*

- In hospital
- Out of hospital
- Unknown

Neurological dysfunction categories:*

Other, specify:*

Causative or contributing factors to the neurological dysfunction AE (check all that apply):*

- Patient not taking anticoagulation medication properly
- If patient receiving warfarin then, evidence of INR above target range
- If patient receiving warfarin then, evidence of INR below target range
- If patient receiving heparin then, evidence of INR above target range
- If patient receiving heparin then, evidence of INR below target range
- Complexities of Medical Management
- Unknown

Details of CNS event:*

Other, specify:*

Location of CNS event:*

Other, specify:*

Method of diagnosis of CNS event:*

Other, specify:*

Description of clinical event:*

Stroke severity:*

Other, specify:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

Specify:*

Surgical intervention:* YES NO UNK

Drug intervention:* YES NO UNK

Treatment:* Heparin
 Thrombolytics
 Anti-Seizure
 None of the above

Did this Neurological Dysfunction Adverse Event contribute to the patient's death:* YES NO UNK

Was there a device malfunction?* YES NO UNK

Date of onset:* mm/dd/yyyy ST=

Location of patient:* In hospital Out of hospital Unknown

Major pump unit involved (check all that apply):* Blood Pump
 Drive Unit Failure

External Control System Failure

Device Thrombosis

Blood Pump Specify:*

Drive Unit Failure Specify:*

External Control System Failure Specify:*

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

External Battery Malfunction

Internal Battery Malfunction

External Controller Malfunction

Internal Controller Malfunction

Driveline Malfunction

Inflow Graft Malfunction/Malposition

Outflow Graft Malfunction/Malposition

Pump Drive Unit Malfunction

TET System Malfunction

Inflow Valve

Outflow Valve

Volume Compensator Malfunction

Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Other, specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

- Patient noncompliance in device maintenance and protection
- Patient error in caring for system
- Inadequate instructions from caregivers
- No specific contributing cause identified

Device malfunction intervention (check all that apply):*

- Replacement of Internal Battery
- Replacement of External Battery
- Replacement of External Controller
- Replacement of Internal Controller
- Replacement of Driveline
- Replacement of Inflow Graft
- Replacement of Outflow Graft
- Replacement of Pump
- Replacement of TET System
- Replacement of Pump Valve
- Replacement of Volume Compensator
- Replacement of Other Component, specify
- Switch from Vented Electric to Pneumatic-mode
- Other Interventions, specify
- None
- Unknown

Specify component:*

Other, specify:*

Surgical procedure required:*

- YES
- NO
- UNK

Device explanted:*

- YES
- NO
- UNK

Device malfunction adverse event cause patient's death:*

- YES
- NO
- UNK

Death

Is the patient deceased?*

- YES
- NO

Death date:*

 mm/dd/yyyy

ST=

Was device functioning normally?:*

- YES
- NO
- UNK

Was there an operation associated with device malfunction?:*

- YES
- NO
- UNK

Post mortem device explant?*

- YES
- NO
- UNK

Did device go to manufacturer?*

YES NO UNK

Location of death:*

In hospital Out of hospital Unknown

Timing of death:*

Expected Unexpected Unknown

Autopsy: *

YES NO UNK

Primary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Explant

Was the device explanted/patient transplanted?*

YES NO

Device explanted:*

Explant date:*

mm/dd/yyyy

ST=

Explant reason:*

Other, specify:*

Transplant date:*

mm/dd/yyyy

ST=

Waitlist ID:*

Quality of Life

Did the patient complete a EuroQol form:*

YES NO UNK

Displays when patient completed a EuroQol form

Mobility:*

Self care:*

Usual Activities (e.g. work, study, housework, family or leisure activities)*

Pain/discomfort:

Anxiety/depression:*

Your own health state today (0-100). 0=worst, 100=best:*

Have you experienced serious illness?* YES NO

Has your family experienced serious illness?* YES NO

Have you experienced serious illness in caring for others?* YES NO

Age in years:*

Sex:* Male Female

Are you:*

Do you now, or did you ever, work in health or social services:* YES NO

In what capacity:*

Which of the following best describes your main activity:*

Other, specify:*

What is the highest level of education you have completed:*

Zip code (if known):

Displays when patient did not complete a EuroQol form

Reason (as stated by patient) why the EUroQoL was not completed:*

Other, specify*

Reason (as stated by coordinator) why the EUroQoL was not completed:*

Other, specify*

Trailmaking Data

Status:*

Time:* sec

Enter Information You Are Reporting

Rehospitalization, Adverse Events, Death or Explant. All events below have default answers as ?No?. Please answer ?Yes? to any of these events that apply and fill out all of that event?s information.

Please enter the date of the event you are reporting:*

 mm/dd/yyyy

Please enter a label describing this event:*

Rehospitalization

Was there an occurrence of rehospitalization?*

YES NO

Date of admission:*

 mm/dd/yyyy

ST=

Discharge associated with this hospitalization*

 mm/dd/yyyy

ST=

Reason for admission (check all that apply):*

- Cardiac Arrhythmia
- Bleeding
- Cardiac Tamponade
- Hematoma
- Hemolysis
- Hepatic Dysfunction
- Hypertension
- Infection
- GI Disorder
- Pulmonary Disorder
- Limb vascular complication
- Pulmonary Embolism/Hemorrhage
- Planned Procedure, specify
- Device Malfunction
- Myocardial infarction
- Neurological Dysfunction
- Psychiatric episode
- Renal Dysfunction
- Right Heart Failure
- Non-CNS Thromboembolic (TE) Event
- Wound Complication
- Unknown

Other, specify

Procedure:*

Specify:*

Rehospitalization intervention:*

Type of surgical procedure:*

Specify:*

Type of cardiac procedure:*

Other procedure:*

Specify:*

Enter CVP:* mm/Hg ST=

Enter PA systolic pressure:* mm/Hg ST=

Enter PA diastolic pressure:* mm/Hg ST=

Enter PCW pressure:* mm/Hg ST=

Enter cardiac output:* L/min ST=

Adverse Events Appendix A: Adverse Event Definitions

Was there a major infection?*

YES NO UNK

Date of onset:*

ST=

Location of patient:* In hospital Out of hospital Unknown

- Location of infection: (check all that apply)*
- Pump / related - Drive Line
 - Pump / related - Pump Pocket
 - Pump / related - Pump Interior
 - Positive Blood cultures
 - Line Sepsis
 - Pulmonary
 - Urinary Tract
 - Mediastinum
 - Peripheral Wound
 - GI
 - Unknown
 - Other, specify

Specify:*

Type of infection:*

Causative or contributing factors to

the infection AE:
(check all that apply)*

- Patient condition
- Patient non-compliance with Medications
- Patient non-compliance with Device Maintenance
- Patient non-compliance with Followup Visits
- Device related
- Complexities of Medical Management
- Unknown

Intervention:*

Infection contribute to Death:*

- YES NO UNK

Was there a neurological dysfunction?*

- YES NO UNK

Date of onset:*

 mm/dd/yyyy

ST=

Location of patient:*

- In hospital Out of hospital Unknown

Neurological dysfunction categories:*

Other, specify:*

Causative or contributing factors to the neurological dysfunction AE
(check all that apply):*

- Patient not taking anticoagulation medication properly
- If patient receiving warfarin then, evidence of INR above target range
- If patient receiving warfarin then, evidence of INR below target range
- If patient receiving heparin then, evidence of INR above target range
- If patient receiving heparin then, evidence of INR below target range
- Complexities of Medical Management
- Unknown

Details of CNS event:*

Other, specify:*

Location of CNS event:*

Other, specify:*

Method of diagnosis of CNS event:*

Other, specify:*

Description of clinical event:*

Stroke severity:*

Other, specify:*

Anticoagulant therapy at time of event (check all that apply):*

- Warfarin
- Heparin

- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

Specify:

Surgical intervention:*

- YES
- NO
- UNK

Drug intervention:*

- YES
- NO
- UNK

Treatment:*

- Heparin
- Thrombolytics
- Anti-Seizure
- None of the above

Did this Neurological Dysfunction Adverse Event contribute to the patient's death:*

- YES
- NO
- UNK

Was there a device malfunction?*

- YES
- NO
- UNK

Date of onset:*

mm/dd/yyyy

ST=

Location of patient:*

- In hospital
- Out of hospital
- Unknown

Major pump unit involved (check all that apply):*

- Blood Pump
- Drive Unit Failure
- External Control System Failure
- Device Thrombosis

Blood Pump Specify:

Drive Unit Failure Specify:

External Control System Failure Specify:

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

- External Battery Malfunction
- Internal Battery Malfunction
- External Controller Malfunction
- Internal Controller Malfunction
- Driveline Malfunction
- Inflow Graft Malfunction/Malposition
- Outflow Graft Malfunction/Malposition
- Pump Drive Unit Malfunction
- TET System Malfunction
- Inflow Valve
- Outflow Valve
- Volume Compensator Malfunction
- Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Other, specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

- Patient noncompliance in device maintenance and protection
- Patient error in caring for system
- Inadequate instructions from caregivers
- No specific contributing cause identified

Device malfunction intervention (check all that apply):*

- Replacement of Internal Battery
- Replacement of External Battery

- Replacement of External Controller
- Replacement of Internal Controller
- Replacement of Driveline
- Replacement of Inflow Graft
- Replacement of Outflow Graft
- Replacement of Pump
- Replacement of TET System
- Replacement of Pump Valve
- Replacement of Volume Compensator
- Replacement of Other Component, specify
- Switch from Vented Electric to Pneumatic-mode
- Other Interventions, specify
- None
- Unknown

Specify component:*

Other, specify:*

Surgical procedure required:* YES NO UNK

Device explanted:* YES NO UNK

Device malfunction adverse event cause patient's death:* YES NO UNK

Were there any other adverse events?* YES NO

ex: bleeding, cardiac arrythmia, pericardial fluid, hemolysis, hepatic dysfunction, hypertension, MI, psychiatric episode, renal dysfunction, respiratory failure, RHF, thromboembolism, wound dehiscence, other serious adverse event

- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise since last INTERMACS report/last followup?*

YES NO UNK

Event Date:* mm/dd/yyyy ST=

Type of cardiac arrhythmia?*:

Pericardial Fluid Collection

Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?*

YES NO UNK

Event date.:* mm/dd/yyyy ST=

Signs of tamponade:* YES NO UNK

Method of drainage:* OP Cath Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup?*

YES NO UNK

Plasma-free hemoglobin measurement:* mg/dL ST=

Hematocrit measurement:* % ST=

Patient has Hyperbilirubinemia (Total Bilirubin > 2 mg/dl):* YES NO UNK

Cause of Hemolysis:*
 Other, specify:*

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:* YES NO UNK

Total bilirubin measurement:* mg/dL ST=

SGOT/AST measurement:* u/L ST=

SGPT/ALT measurement:* u/L ST=

Hypertension

Did onset bp >= 140mm Hg systolic or 90mm Hg diastolic (Pediatric patient: > 95th percentile, see definition) occur since last INTERMACS report/last followup?:* YES NO UNK

Systolic bp:* mm Hg ST=

Diastolic bp:* mm Hg ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup/admission?:* YES NO UNK

Date of event:* mm/dd/yyyy ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:* YES NO UNK

Renal Dysfunction

Did renal dysfunction requiring dialysis occur since last INTERMACS report/last followup?:* YES NO UNK

Event date.:* mm/dd/yyyy ST=

Dialysis duration:* weeks ST=

Peak creatinine measurement:* mg/dL ST=

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:*

- YES NO UNK

Date of event: * mm/dd/yyyy

ST=

Intubation duration: * days

ST=

Was a tracheotomy performed?:* YES NO UNK

Right Heart Failure

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:*

- YES NO UNK

Event date.:* mm/dd/yyyy

ST=

Check all signs/symptoms that apply:*

- CVP > 18 mmHg
- CI < 2.0 L/min/M2
- Ascites
- Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?:*

- YES NO UNK

Date: * mm/dd/yyyy

ST=

Location: *

Other acute perfusion deficit: *

Confirmation source: *

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux

- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- Deep Vein thrombosis
- Pulmonary Embolis
- Other, specify
- Unknown
- None

Specify event:*

Enter deep vein thrombosis date:* mm/dd/yyyy

ST=

Enter pulmonary embolis date:* mm/dd/yyyy

ST=

Enter other date:* mm/dd/yyyy

ST=

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify:*

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup?*

YES NO UNK

Date:*

mm/dd/yyyy

ST=

Other

Other Major Serious Adverse Event since last INTERMACS report/last followup:

Death

Is the patient deceased?*

YES NO

Death date:*

mm/dd/yyyy

ST=

Was device functioning normally?:*

YES NO UNK

Was there an operation associated with device malfunction?:*

YES NO UNK

Post mortem device explant?*

YES NO UNK

Did device go to manufacturer?*

YES NO UNK

Location of death:*

In hospital Out of hospital Unknown

Timing of death:*

Expected Unexpected Unknown

Autopsy: *

YES NO UNK

Primary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Explant

Was the device explanted/patient transplanted?*

YES NO

Device explanted:*

Explant date:*

ST=

Explant reason:*

Other, specify:*

Transplant date:*

ST=

Waitlist ID:*

Blood & Tissue

Myocardial tissue obtained:*

YES NO UNK

During:*

Implant Explant

Date:*

mm/dd/yyyy

ST=

BSI# (from label):*

ST=

Tissue processing (check all that apply):*

- Snap frozen
- Formalin
- Unknown

Venous blood obtained:*

YES NO UNK

Date:*

mm/dd/yyyy

ST=

BSI# (from label):*

ST=

Blood processing (check all that apply):*

- Buffy coat
- Serum
- Unknown

This page intentionally left blank.

Appendix VI

INTERMACS Informed Consent and HIPAA Authorization



Interagency Registry of Mechanically Assisted Circulatory Support

Patient Consent Form for Participation in Research

Sponsor: -----od Institute (NHLBI)

Principal Investigator:

Phone number:

INFORMED CONSENT

You are being asked to take part in this registry because

- you are receiving, or have received, a mechanical circulatory support device (MCSD).

A registry is a place where data, records, and sometimes laboratory samples are kept and made available for research. This registry will collect and analyze clinical information and laboratory data from all patients who are having an MCSD implanted for supporting the circulation. This registry includes approximately 80 hospitals within the United States for a period of four years starting March 1, 2006. The broad purpose of the registry is to gather information to help understand and improve the lives of patients with advanced heart failure.

YOUR PARTICIPATION IS VOLUNTARY

This is a consent form. It gives you information about the registry. You are free to ask questions about this study at any time. If you agree to take part in this registry, you will be asked to sign this consent form. The study coordinator will make you a copy of this form to keep.

Before you learn about the registry, it is important that you know the following:

- Your participation is totally voluntary and will not effect your care in any way.
- You may decide not to take part or to leave the study at any time without losing your medical care benefits.

WHAT IS THE PURPOSE OF THIS REGISTRY?

Over the last twenty years, mechanical circulatory support devices (MCSD) have been developed to help the failing heart. MCSDs have been used successfully to support patients until they get a heart transplant, as treatment until they recover, as well as for permanent implantation (placement in the body) or "destination therapy". It is expected that the number of MCSD implantations will increase in future years. This registry will allow scientists to study patient characteristics, device function, implantation procedures, and the possible adverse events that can arise with MCSD placement. The registry will also be linked with other existing databases, such as the transplant registry (SRTR) that will allow us to understand how the MCSD affects the outcome following transplant as well.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

If you decide to take part in this study and sign the informed consent, you will:

- Allow research staff within the hospital to review your medical chart for information on your medical history and medications you have taken or may be currently taking. This information will be entered into a confidential database.
- You will complete a brief questionnaire to describe your quality of life, and you will complete a brief test to measure the function of your nervous system (neurocognitive test).

The medical chart review and abstractions will be done:

- before your implant,
- 1 week after implant,
- 1 month after implant,
- 3 months after implant,
- 6 months after implant and every six months thereafter.

The brief quality of life questionnaire and the a neurocognitive test will be done:

- before your implant,
- 3 months after implant,
- 6 months after implant and every six months thereafter.

If you receive a heart transplant, your "follow-up" will occur in the UNOS (United Network or Organ Sharing) transplant database. You will allow your registry data to be merged with transplant data and analyzed by registry investigators. If your MCSD is removed and you have recovered, you will have your medical information followed for one more year after removal.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is possible that about **8,000** people will take part in this registry:

- 2,000 patients per year for 4 years.
- The 2000 patients per year will come from up to 80 participating hospitals nationwide.

HOW LONG WILL I BE IN THIS STUDY?

Participation in the registry begins when this consent form is signed and continues for as long as you have a MCSDD implanted. Following heart transplant, death, or 1 year after removal due to recovery, data collection will cease. If you transfer to another institution that participates in this registry, you will be asked to sign another consent form for continued participation. You are free to leave the study or withdraw your consent at any time, even after you have signed this consent. If the hospital that implanted your MCSDD discontinues participation in the registry, then your participation in this study will end.

WHAT ARE THE RISKS OF THE REGISTRY?

The risks for participation in this registry are considered very small. The data collection will be confidential and there will be no risk to you. The quality of life questionnaire and the Trailmaking neurocognitive test will take some of your time - approximately 20 minutes for the quality of life questionnaire and 5 minutes for the Trailmaking test. There are some questions that some may consider sensitive. You can choose not to answer any questions that you do not want to.

WHAT ARE THE BENEFITS OF THE REGISTRY?

There is no direct benefit to you from being in this registry. However, knowledge gained from the registry may help those with advanced heart failure. A potential indirect benefit is that you may help doctors and scientists better understand how the MCSDD improve or do not improve life for heart failure patients. You will be given any new information during the course of this study concerning significant treatment findings that may affect your willingness to continue your participation.

WHAT ABOUT CONFIDENTIALITY?

All information collected in this registry will be held confidential to the extent permitted by law. No published or unpublished report or visual or speaking presentation about this study will include any material that will identify you as a participant in this study. Your name, date of birth, and only the last 5 digits of your social security number, and hospital medical records number (optional) will be entered into the confidential database at UNOS. This is so UNOS can link your data with the transplant database in the event that you receive a heart transplant.

Your confidential information will not be available to anyone outside of UNOS, and only UNOS employees that work directly with the registry will be exposed. UNOS complies with all national patient privacy regulations. All of their data systems feature multiple levels of security, which protect patient data by the most stringent requirements. They are fully compliant with the Health Insurance Portability and Accountability Act (HIPPA) and are certified by the Health Resources and Services Administration (HRSA). In addition, all UNOS employees have passed federal HHS background checks for government clearance. They are audited annually by HRSA for compliance. Monitors and print outs are in areas that are badge access only. Access to the production databases are on a need-to-know access only.

In certain circumstances, (*name of institution's*) Institutional Review Board (IRB) may request a copy of your records. The job of the IRB is to make sure that volunteers in studies are protected. If they ask for a copy of your records, we will give it to them. In addition, under the guidelines of the Federal Privacy Act, the sponsoring agency, the National Heart Lung and Blood Institute and the study monitors at United Network of Organ Sharing (UNOS), the Clinical Research Organization for this study, may also periodically request to review your records. Their job is to make sure that the registry is doing what it is supposed to and that volunteers are protected. If they ask to see your records, we will let them.

Investigators for INTERMACS, NHLBI, representatives from the MCS D manufacturer, the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) will use your information to better understand how the MCS D improve or do not improve life for heart failure patients.

To help us protect your privacy, INTERMACS has obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that this does not prevent you or a member of your family from releasing information about yourself or your involvement in this registry if you want to. Note however, that if an insurer or employer learns about your participation, and you say it is all right for them to have this research information, then the investigator may not withhold this information from them. This means that you and your family must also actively protect your own privacy. You have to be careful about whom you permit to look at your research information.

WHAT ARE THE COSTS TO ME?

There are no costs to you for participation in this registry. As usual, you and/or your insurance company will be responsible for any costs that are part of your routine care.

WILL I RECEIVE ANY PAYMENT?

You will not be paid or offered any other compensation for participating in this registry. You will not receive any medications through this registry.

WHAT HAPPENS IF I AM INJURED?

There is minimal risk associated with this registry data collection. In the rare instance that you are injured as a result of being in this registry, you will be given immediate treatment. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation through either this institution or the National Institutes of Health (NIH).

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study AT ANY TIME without penalty, loss of benefits, or change in your present or future care. You will be treated the same no matter what you decide. We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, tell the study staff. You are not giving up any of your legal rights by signing this consent form.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

If you ever have questions about this study or in case of research-related injuries, you should contact (*name of investigator*) at (*telephone number*). If you have questions about research subjects' rights, you can call (*name and title of IRB member*) at (*telephone number*).

STATEMENT OF CONSENT

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

The details of this study have been explained to you and you have been given the opportunity to ask any questions you wish regarding this study. The doctor or other person performing this research study has told you that your participation in this study is voluntary. You may be a subject in it only if you wish, and you may refuse to participate or stop participating at any time

without any way affecting your future treatment at this hospital, or your future relations with the hospital or its employees. By signing this consent form, you are voluntarily agreeing to take part in this study and giving your permission for the study investigators to collect and use the information needed for the purposes of this study. If you voluntarily agree to take part in this study, please sign your name below.

Participant Name (print) Participant Signature Date

Witness Name (print) Witness Signature Date

PI or Designee's statement:

I have reviewed this study and the consent form with the subject. To the best of my knowledge, she understands the purpose, procedures, risks, and benefits of the study.

PI or Designee Name (print) PI or Designee Signature Date

NOTE: This consent form with the original signatures **MUST** be retained on file by the principal investigator. A copy must be given to the volunteer. A copy should be placed in the volunteer's medical record, if applicable.



Interagency Registry of Mechanically Assisted Circulatory Support

Authorization for the Use and Disclosure of Protected Health Information (HIPAA)

Sponsor: _____ Institute (NHLBI)

Principal Investigator: _____

Phone number: _____

This section is asking you to authorize the use and disclosure of your health information for the registry named *Interagency Registry for Mechanically Assisted Circulatory Support*. To do that you need to know:

- The kind of health information about you that the registry will collect and use; this information includes:
 - interviews about your health and quality of life;
 - laboratory test results;
 - and medical chart review.

- The reasons that we are doing this study, which have been described to you earlier, can be found in the Informed Consent section “WHY IS THIS STUDY BEING DONE?”

- The persons who will collect and use your information for this study:
 - Dr. (insert site PI) (or whoever may replace this doctor) and the research staff are responsible for collecting this information here at (insert institution name).
 - This clinical site will send your information through a secure website to the United Network for Organ Sharing (UNOS), which maintains of the database for the registry.
 - Investigators for INTERMACS, including representatives from device manufacturers, the National Heart Lung and Blood Institute, the Food and Drug Administration, and the Center for Medicare and Medicaid Services, will use your information to better understand how the MCS D improve or do not improve life

for heart failure patients, **but they will not know your name or social security number (partial).**

- The people named earlier, see Informed Consent section “WHAT ABOUT CONFIDENTIALITY?”, who make sure that your rights and safety are protected and that study findings are accurate may also need to see information about you in your records.
- This authorization will end at the end of this study when all the information has been evaluated.
- You can stop the use of your information in this research study by sending a written request to Dr. (*insert name of PI*) (*or whoever may replace this doctor*). If you decide to withdraw your authorization:
 - No more information will be collected from you or your records for the research study from the time the written request is received;
 - The study will only use the information it has already collected from you before you sent the written request.
- When you sign this document and authorize the use and disclosure of your health information for this research, the information disclosed may no longer be protected by the federal privacy regulations found at 45 CFR Part 164. But, the researchers for this study can only use or disclose your health information for purposes that are approved by an Institutional Review Board or as required by law or regulation.

STATEMENT OF CONSENT

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

The details of this authorization have been explained to you and you have been given the opportunity to ask any questions you wish.

If you voluntarily agree to allow the researchers to use and disclose your health information for the purpose of this study, please print and sign your name below.

Participant Name (print)

Participant Signature

Date

Witness Name (print)

Witness Signature

Date

PI or Designee's Statement:

I have reviewed the authorization for the use and disclosure of protected health information with the subject. To the best of my knowledge, she understands the meaning of this authorization.

PI or Designee Name (print)

PI or Designee Signature

Date

Note: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the volunteer. A copy should be placed in the volunteer's medical record, if applicable.