REVIVAL Study
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Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-001 Documentation of Informed Consent - Patient

Baseline A

Date of Informed Consent: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Did patient consent to genomic DNA blood collection?

O Yes **O** No

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-002 Inclusion Criteria

Baseline A

Inclusion criteria #1 through #8 and #10 and #11 need to be answered "Yes" for the subject to be eligible to continue in the Registry. To meet criterion #9, any <u>single</u> item i through x must be answered "Yes" to be eligible.

1.	Ambulatory	**O** Yes **O** No
2.	Chronic systolic heart failure ≥ 12 months	**O** Yes **O** No
3.	NYHA II - IV for at least 45 of the last 60 days	**O** Yes **O** No
4.	Last documented left ventricular ejection fraction ≤ 35% by any imaging modality	**O** Yes **O** No
5.	Age 18-80 years	**O** Yes **O** No
6.	Currently under the care of a cardiologist at study site	**O** Yes **O** No
7.	On appropriate evidenced-based heart failure medications - ACE inhibitor, ARB or sacubitril/valsartan (LCZ-696); beta blocker; aldosterone antagonist; hydralazine/long-acting nitrate (required of African-American subjects only) for ≥ 3 months absent contraindications or intolerances	**O** Yes **O** No
8.	Has ICD or CRT-D. If CRT-D, present for ≥ 3 months	**O** Yes **O** No
9.	Demonstrated advanced heart failure, including any of the following:	

RVREG-002 Inclusion Criteria

	i.	Serum sodium ≤ 135 mEq/L (*obtained as an outpatient using values obtained within the prior 90 days*)	**O** Yes **O** No **O** Not available
	ii.	Serum BNP ≥ 750 pg/mL or NT-proBNP ≥ 3000 pg/mL (*obtained as an outpatient using values obtained within the prior 90 days*)	**O** Yes **O** No **O** Not available
	iii.	Seattle Heart Failure Model (SHFM) one year predicted survival ≤ 85% (*obtained within the prior 90 days*) ***(****If* ***Yes****, send screen shot via MiShare to the DCC of the SHFM webpage calculation showing % survival at one year.)*	**O** Yes **O** No **O** Not available
	iv.	Heart Failure Survival Score (HFSS) ≤ 7.19 (*Peak VO_2 obtained within the prior 365 days, all other components of the HFSS obtained within the prior 90 days*)	**O** Yes **O** No **O** Not available
	v.	Peak VO_2 ≤ 55% of predicted for age by Wasserman equation or ≤ 14 ml/kg/min, with RER ≥ 1.05 (*obtained within the prior 365 days*)	**O** Yes **O** No **O** Not available
	vi.	VE/VCO_2 slope ≥ 40 (*obtained within the prior 365 days*)	**O** Yes **O** No **O** Not available
	vii.	6 Minute Walk Test (6MWT) distance ≤ 350 meters without significant non-cardiac limitation (*obtained within the prior 90 days*)	**O** Yes **O** No **O** Not available

RVREG-002 Inclusion Criteria

	viii.	Currently listed as Heart Transplant Status UNOS 2 due to heart failure limitation	**O** Yes **O** No **O** Not available
	ix.	History of one (1) hospitalization (≥ 24 hours) for acute or acute on chronic heart failure in the past year with additional history to include Serum BNP ≥ 500 pg/mL or NT-proBNP ≥ 2000 pg/mL (*obtained as an outpatient using values obtained within the prior 90 days)*	**O** Yes **O** No **O** Not available
	x.	History of two (2) hospitalizations (≥ 24 hours) for acute or acute on chronic heart failure in the past year	**O** Yes **O** No **O** Not available
10.	Willingness to continue to receive heart failure care from the enrolling advanced heart failure clinic over the next two (2) years and to come for all scheduled study visits		**O** Yes **O** No
11.	Written informed consent given		**O** Yes **O** No

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-003 Exclusion Criteria

Baseline A

All Exclusion Criteria need to be answered "No" for the subject to be eligible to continue in the Registry.

1.	Known serious medical problem other than heart failure that would be expected to limit 2-year survival (≥ 50% mortality within 2 years from non-heart failure diagnosis)	**O** Yes **O** No
2.	Patient is not likely to be compliant with the protocol, in the opinion of the Investigator	**O** Yes **O** No
3.	Currently hospitalized	**O** Yes **O** No
4.	Current use of an intravenous inotrope	**O** Yes **O** No
5.	Primary functional limitation from non-cardiac diagnosis even if not likely to limit survival	**O** Yes **O** No
6.	Chronic hemodialysis or peritoneal dialysis or serum creatinine value of ≥ 3 mg/dL at time of enrollment	**O** Yes **O** No
7.	Cardiac amyloidosis, cardiac sarcoidosis, constrictive pericardial disease, active myocarditis or congenital heart disease with significant structural abnormality	**O** Yes **O** No
8.	Hypertrophic cardiomyopathy unless dilated LV and no outflow gradient	**O** Yes **O** No
9.	Cardiac conditions that are amenable to surgical or percutaneous procedures (other than VAD or transplant) that would substantially improve prognosis and for which this subject is a reasonable candidate, regardless of whether the procedure will or will not be performed	**O** Yes **O** No
10.	Uncorrected hyperthyroidism or hypothyroidism	**O** Yes **O** No
11.	Pregnancy	**O** Yes **O** No

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-004 Demographics

Baseline A

Date of Birth: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Sex:

- **O** Male
- **O** Female

Ethnicity: *(select one)*

- **O** Hispanic or Latino
- **O** Non-Hispanic or Non-Latino
- **O** Unknown/Undisclosed

Race: (*select all that apply*)

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

Is the last five digits of subject's social security number available?

- **O** Yes
- **O** Not available
- **O** Undisclosed

*If **Yes***, provide **last five digits** of subject's social security number:

_____ _____ _____ _____ _____

RVREG-004 Demographics

Medicare Claim Number (HIC number):

____ ____ ____ - ____ ____ - ____ ____ ____ ____ / ____ ____ ***or*** **O** Not applicable

Marital Status:

- **O** Single
- **O** Married
- **O** Domestic Partner
- **O** Divorced/Separated
- **O** Widowed
- **O** Unknown

Is the subject currently working for income or attending school:

- **O** Yes
- **O** No
- **O** Unknown

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

- **O** Working or attending school full time
- **O** Working or attending school part time due to demands of treatment
- **O** Working or attending school part time due to disability
- **O** Working or attending school part time due to patient choice
- **O** Working or attending school part time reason unknown
- **O** Working or attending school part time vs. full time unknown
- **O** Working part time due to insurance conflict
- **O** Working part time due to inability to find full time work

*If **No***, select the one main reason subject is not working for income or attending school:

- **O** Disability
- **O** Demands of treatment
- **O** Insurance conflict
- **O** Inability to find work
- **O** Subject choice - homemaker
- **O** Subject choice - retired
- **O** Subject choice – other
- **O** N/A - hospitalized
- **O** Unknown

What is the subject's highest educational level?

- **O** None
- **O** Grade school (1-8)
- **O** High school (9-12)
- **O** Attended college/technical school
- **O** Associate degree
- **O** Bachelor degree
- **O** Post-college Graduate degree
- **O** Unknown

What type of health insurance does the subject have? (*select all that apply*)

- ❒ None
- ❒ Medicare – Fee-for-Service (standard Medicare)
- ❒ Medicare - Other (Medicare Advantage, Medicare HMO, Medicare PPO, etc.)
- ❒ Medicaid
- ❒ Tricare (formerly CHAMPUS)
- ❒ State or Federal plans under the Affordable Care Act
- ❒ Workers Compensation
- ❒ Private/commercial insurance (BCBS, Cigna, Aetna, United Health, etc.)
- ❒ Other, specify: _____

RVREG-004 Demographics

What is the subject's approximate annual household income from all sources before taxes?

- **O** Less than 20,000
- **O** 20,000-39,999
- **O** 40,000 - 59,999
- **O** 60,000 - 79,999
- **O** 80,000 - 99,999
- **O** >99,999
- **O** Refused

Was this subject previously enrolled in MedaMACS?

- **O** Yes
- **O** No
- **O** Unknown

Was this subject previously enrolled in REVIVE-IT?

- **O** Yes
- **O** No
- **O** Unknown

In the opinion of the Investigator, do you feel the subject is competent in the English language to complete the study questionnaires?

- **O** Yes
- **O** No

*If **No***, this subject should **not** complete the subject-completed Quality of Life questionnaires.

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-005 New York Heart Association Functional Class (NYHA Class)

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Person Performing Assessment: _____
(please print name clearly)

NYHA Class:

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

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

O Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.

O Class IIIb: Very marked limitation of physical activity due to symptoms with minimal exertion.

O Class IV: Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-006 INTERMACS® Patient Profile

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Person Performing Assessment: _____
(please print name clearly)

INTERMACS® Patient Profile: Select the **one** INTERMACS® Patient Profile that most closely characterizes the patient's current clinical status.

O INTERMACS® 1: Critical cardiogenic shock describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. This patient can have modifier A or TCS (see 'Modifiers' below).

O INTERMACS® 2: Progressive decline describes a 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. Patient Profile 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. This patient can have modifiers A or TCS.

RVREG-006 INTERMACS® Patient Profile

O INTERMACS® 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) 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 a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 3 can have modifier A, and if in the hospital with circulatory support can have modifier TCS. If patient is at home most of the time on outpatient inotropic infusion, this patient can have a modifier FF if he or she frequently returns to the hospital.

O INTERMACS® 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living (ADL). He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe lower extremity edema. This patient 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. This patient can have modifiers A and/or FF.

O INTERMACS® 5: Exertion Intolerant describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant. This patient can have modifiers A and/or FF.

RVREG-006 INTERMACS® Patient Profile

O INTERMACS® 6: Exertion Limited also describes a patient who is comfortable at rest without evidence of fluid overload, but who is 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 of any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year. This patient can have modifiers A and/or FF.

O INTERMACS® 7: Advanced NYHA Class 3 describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. This patient may have a modifier A only.

RVREG-006 INTERMACS® Patient Profile

INTERMACS® Modifier Present: **O** No **O** Yes

*If **Yes**, check all that apply:*

- ❑ **A - Arrhythmia.** This modifier can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to the overall clinical course. This includes frequent shocks from ICD or requirement for external defibrillator, usually more than twice weekly.

- ❑ **TCS –Temporary Circulatory Support.** This modifier can modify only patients who are confined to the hospital, Patient Profiles 1, 2, and 3 (a patient who is listed as Patient Profile 3 stable on inotropes who has been at home until elective admission for implantable VAD cannot have a TCS modifier.) Support includes IABP, ECMO, TandemHeart, Levitronix, BVS 5000 or AB5000, Impella.

- ❑ **FF – Frequent Flyer.** This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. NOTE: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-006 INTERMACS® Patient Profile

O LVAD INTERMACS

This form is ONLY to be completed at the time of LVAD implant.

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Person Performing Assessment: _____
(please print name clearly)

INTERMACS® Patient Profile: Select the **one** INTERMACS® Patient Profile that most closely characterizes the patient's current clinical status.

O INTERMACS® 1: Critical cardiogenic shock describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. This patient can have modifier A or TCS (see 'Modifiers' below).

O INTERMACS® 2: Progressive decline describes a 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. Patient Profile 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. This patient can have modifiers A or TCS.

RVREG-006 INTERMACS® Patient Profile

O INTERMACS® 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) 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 a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 3 can have modifier A, and if in the hospital with circulatory support can have modifier TCS. If patient is at home most of the time on outpatient inotropic infusion, this patient can have a modifier FF if he or she frequently returns to the hospital.

O INTERMACS® 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living (ADL). He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe lower extremity edema. This patient 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. This patient can have modifiers A and/or FF.

O INTERMACS® 5: Exertion Intolerant describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant. This patient can have modifiers A and/or FF.

RVREG-006 INTERMACS® Patient Profile

O INTERMACS® 6: Exertion Limited also describes a patient who is comfortable at rest without evidence of fluid overload, but who is 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 of any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year. This patient can have modifiers A and/or FF.

O INTERMACS® 7: Advanced NYHA Class 3 describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. This patient may have a modifier A only.

RVREG-006 INTERMACS® Patient Profile

INTERMACS® Modifier Present: **O** No **O** Yes

*If **Yes**, check all that apply:*

- ❑ **A - Arrhythmia.** This modifier can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to the overall clinical course. This includes frequent shocks from ICD or requirement for external defibrillator, usually more than twice weekly.

- ❑ **TCS –Temporary Circulatory Support.** This modifier can modify only patients who are confined to the hospital, Patient Profiles 1, 2, and 3 (a patient who is listed as Patient Profile 3 stable on inotropes who has been at home until elective admission for implantable VAD cannot have a TCS modifier.) Support includes IABP, ECMO, TandemHeart, Levitronix, BVS 5000 or AB5000, Impella.

- ❑ **FF – Frequent Flyer.** This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. NOTE: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-007 Physical Exam/Vitals

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Heart Rate (Beats/min): __ __ __ ***or*** **O** Not Done

Systolic Blood Pressure (mmHg): __ __ __ ***or*** **O** Not Done

Diastolic Blood Pressure (mmHg): __ __ __ ***or*** **O** Not Done

Jugular Venous Pressure (cm): __ __ ***or*** **O** Not Done

S3 Gallop:

O Present
O Absent
O Not Done

S4 Gallop:

O Present
O Absent
O Not Done

RVREG-007 Physical Exam/Vitals

Peripheral Edema:

- **O** None
- **O** 1+
- **O** 2+
- **O** >3+
- **O** Not Done

Ascites:

- **O** Yes
- **O** No
- **O** Not Done

Hepatomegaly:

- **O** Present
- **O** Absent
- **O** Not Done

Respiratory Rate (Breaths/min): __ __ __ ***or*** **O** Not Done

Height: __ __ __ . __ **O** inches **O** cm

Weight (pounds): __ __ __ . __

NOTE: ***To be calculated by the DCC***

Mean Arterial Blood Pressure (mmHG): _____

Body Surface Area (m^2): _____

Body Mass Index (Weight (Kg)/Height^2 (Meters): _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-008 Hematology

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

NOTE: *If the heart failure subject has historic laboratory results on file that were drawn within 14 days of the assessment date, these results may be used for fulfillment of this visit requirement if, in the opinion of the investigator, the historic laboratory result(s) are highly likely to represent the subject's current health status.*

Date of Blood Draw: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

White blood cell count (K/mm^3): __ __ . __

Hemoglobin (g/dL): __ __ . __

Hematocrit (%): __ __ . __

Platelet count (K/mm^3): __ __ __ __

Lymphocytes (%): __ __ . __

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-009a Chemistry Panel

O Baseline A **O** Baseline B
O Month 12

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

NOTE: *If the heart failure subject has historic laboratory results on file that were drawn within 14 days of the assessment date, these results may be used for fulfillment of this visit requirement if, in the opinion of the investigator, the historic laboratory result(s) are highly likely to represent the subject's current health status.*

Date of Blood Draw: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Sodium (mEq/L): __ __ __

Potassium (mEq/L): __ . __

Blood Urea Nitrogen (mg/dL): __ __ __

Creatinine (mg/dL): __ __ . __

Glucose (mg/dL): __ __ __

Calcium (mg/dL): __ __ . __

Albumin (g/dL): __ . __

SGPT/ALT (Alanine Aminotransferase) (IU/L): __ __ __ __

SGOT/AST (Aspartate Aminotransferase) (IU/L): __ __ __ __

Total Bilirubin (mg/dL): __ __ . __

RVREG-009a Chemistry Panel

Total Cholesterol (mg/dL): __ __ __

Uric Acid (mg/dL): __ __ . __

INR: __ __ . __

NOTE: ***Estimated GFR will be calculated by the DCC at the end of the study***

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-009b Chemistry Panel

O Month 6 **O** Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

NOTE: *If the heart failure subject has historic laboratory results on file that were drawn within 14 days of the assessment date, these results may be used for fulfillment of this visit requirement if, in the opinion of the investigator, the historic laboratory results(s) are highly likely to represent the subject's current health status.*

Date of Blood Draw: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Sodium (mEq/L): __ __ __

Potassium (mEq/L): __ . __

Blood Urea Nitrogen (mg/dL): __ __ __

Creatinine (mg/dL): __ __ . __

Glucose (mg/dL): __ __ __

Calcium (mg/dL): __ __ . __

Albumin (g/dL): __ . __

SGPT/ALT (Alanine Aminotransferase) (IU/L): __ __ __ __

SGOT/AST (Aspartate Aminotransferase) (IU/L): __ __ __ __

Total Bilirubin (mg/dL): __ __ . __

RVREG-009b Chemistry Panel

NOTE: ***Estimated GFR will be calculated by the DCC at the end of the study***

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-010a Medication Log A

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Dose is reported as the total dose of drug administered within a 24-hour period *unless otherwise specified*.

ACE inhibitor: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one)*

O Lisinopril
O Ramipril
O Enalapril
O Captopril
O Fosinopril
O Benazepril
O Trandolapril
O Quinapril
O Other, specify:_____

*If **No**, select reason*:

O Currently on ARB
O Currently on sacubitril/valsartan (LCZ-696)
O Previously documented intolerance
O New intolerance
O Other, specify: _____

RVREG-010a Medication Log A

If previous or new intolerance, specify reasons:

- ❒ Renal failure
- ❒ Hypotension
- ❒ Cough
- ❒ Angioedema
- ❒ Unknown
- ❒ Other, specify: _____

Angiotensin receptor blocker: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one*)

- **O** Losartan
- **O** Valsartan
- **O** Candesartan
- **O** Olmesartan
- **O** Irbesartan
- **O** Telemisartan
- **O** Other, specify:_____

*If **No**, select reason*:

- **O** Currently on ACE inhibitor
- **O** Currently on sacubitril/valsartan (LCZ-696)
- **O** Previously documented intolerance
- **O** New intolerance
- **O** Other, specify: _____

If previous or new intolerance, specify reasons:

- ❒ Renal failure
- ❒ Hypotension
- ❒ Angioedema
- ❒ Unknown
- ❒ Other, specify: _____

RVREG-010a Medication Log A

Sacubitril/valsartan (LCZ-696) **O** Yes **O** No

*If **Yes**,* Total Daily Dose: __ __ __ / __ __ __ mg

*If **No**, select reason*:

- **O** Currently on ACE inhibitor
- **O** Currently on ARB
- **O** Previously documented allergy or intolerance to valsartan or any other ARB or an ACE inhibitor
- **O** Previously documented allergy or intolerance to this combination drug
- **O** Drug is not available
- **O** Drug is available and no allergy or intolerance but clinical decision not to use this combination drug
- **O** Other, specify:_____

Beta-blocker: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg

(*select one*)

- **O** Metoprolol succinate
- **O** Metoprolol tartrate
- **O** Carvedilol
- **O** Carvedilol sustained release
- **O** Bisoprolol
- **O** Atenolol
- **O** Propranolol
- **O** Other, specify:_____

RVREG-010a Medication Log A

*If **No**, select reason*: O Previously documented intolerance
O New intolerance
O Other, specify: _____

If previous or new intolerance, specify reasons:
❒ Bradycardia
❒ Hypotension
❒ Fatigue
❒ Bronchospasm
❒ Unknown
❒ Other, specify: _____

Aldosterone antagonist: O Yes O No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one*) O Spironolactone
O Eplerenone

*If **No**, select reason*: O Previously documented intolerance
O New intolerance
O Other, specify: _____

If previous or new intolerance, specify reasons:
❒ Renal Insufficiency
❒ Hyperkalemia
❒ Gynecomastia
❒ Gastrointestinal
❒ Unknown
❒ Other, specify: _____

RVREG-010a Medication Log A

Long Acting Nitrate: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one*)
O Isosorbide dinitrate
O Isosorbide mononitrate
O Other, specify:_____

*If **No**, select reason*:
O Previously documented intolerance
O New intolerance
O Not indicated
O Other, specify: _____

If previous or new intolerance, specify reasons:
❒ Hypotension or Lightheadedness
❒ Headache
❒ Unknown
❒ Other, specify: _____

RVREG-010a Medication Log A

Hydralazine: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg

*If **No**, select reason*:
O Previously documented intolerance
O New intolerance
O Not indicated
O Other, specify: _____

If previous or new intolerance, specify reasons:
❒ Hypotension or Lightheadedness
❒ Headache
❒ Gastrointestinal
❒ Unknown
❒ Other, specify: _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-010b Medication Log B

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

Dose is reported as the total dose of drug administered within a 24-hour period *unless otherwise specified*.

Loop Diuretic: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one*)
O Furosemide
O Bumetanide
O Torsemide
O Ethacrynic acid

Thiazide or Thiazide-like Diuretic: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ mg
(*select one*)
O Hydrochlorothiazide
O Metolazone
O Chlorothiazide
O Clorthalidone

Digoxin: **O** Yes **O** No

*If **Yes**,* Total Daily Dose: _____ **O** mg **O** mg/mL **O** mcg

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-010b Medication Log B

Antiplatelets: **O** Yes **O** No

NOTE: *These include aspirin, clopidogrel, prasugrel, ticagrelor, dipyridamole.*

Oral Anticoagulant: **O** Yes **O** No

NOTE: *These include warfarin, dabigatran, apixaban, rivaroxaban, edoxaban.*

NOTE: *If subject is chronically on oral anticoagulant but temporarily off for procedure, check "Yes".*

Antiarrhythmic: **O** Yes **O** No

(*If **Yes**, select all that apply)*

- ❒ Amiodarone: Total Daily Dose: _____ mg
- ❒ Other antiarrhythmic

Statin: **O** Yes **O** No

Allopurinol: **O** Yes **O** No

RVREG-010b Medication Log B

PDE-5 Inhibitor: **O** Yes **O** No

***Do not record if used intermittently for erectile dysfunction.**

*If **Yes**,* (*select one*):

O *Tadalafil: Dose: _____ mg
O *Sildenafil: Total Daily Dose: _____ mg
O *Vardenafil: Total Daily Dose: _____ mg

Compliance since previous visit:

How often did the subject have difficulty remembering to take all his/her medications?

O Never/Rarely
O Once in a while
O Sometimes
O Usually
O All the time
O Unknown

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-011 Medical History

Baseline A

Date of first heart failure onset: __ __ __ /__ __ __ __
MON YYYY
(*month is not mandatory if heart failure onset was prior to 2014)*

Number of heart failure-related hospitalizations within the last 12 months:

_____

NOTE*: Do not include hospitalizations for planned procedures (ICD generator change, implantation of CRT-D)*

Etiology

Cardiac Diagnosis/Primary: *(select one)*

- **O** Coronary Artery Disease
- **O** Dilated Myopathy: Chemotherapy induced (e.g., Adriamycin, Herceptin)
- **O** Dilated Myopathy: Alcoholic
- **O** Dilated Myopathy: Familial
- **O** Dilated Myopathy: Idiopathic
- **O** Dilated Myopathy: Myocarditis
- **O** Dilated Myopathy: Post-partum
- **O** Dilated Myopathy: Viral
- **O** Dilated Myopathy: Other, specify: _____
- **O** Hypertrophic cardiomyopathy (dilated)
- **O** Valvular Heart Disease
- **O** Unknown
- **O** Other, specify: _____

Previous Cardiac Operation: **O** No **O** Yes **O** Unknown

*If **Yes***, Type of Previous Cardiac Operation: (*check all that apply*)

- ❒ CABG
- ❒ Aortic valve replacement/repair

RVREG-011 Medical History

- ❒ Mitral valve replacement/repair
- ❒ Tricuspid valve replacement/repair
- ❒ Surgery for aortic aneurysm/dissection
- ❒ Cardiac surgery for congenital heart disease
- ❒ Resection of left ventricular aneurysm or left ventricular remodeling procedure
- ❒ Surgery for ventricular or atrial arrhythmias
- ❒ Other, specify:_____

Number of previous sternotomies and thoracotomies: _____

Arrhythmia: **O** No **O** Yes **O** Unknown

*If **Yes***, specify: (*check all that apply*)

- ❒ Atrial fibrillation or atrial flutter (including paroxysmal)
- ❒ Sustained ventricular tachycardia
- ❒ Ventricular fibrillation
- ❒ Appropriate ICD shock for VT or VF

Comorbidities

Diabetes: **O** No **O** Yes **O** Unknown

Chronic Obstructive Pulmonary Disease: **O** No **O** Yes **O** Unknown

---

Sleep Apnea: **O** No **O** Yes **O** Unknown

*If **Yes***, select the therapy the subject is receiving: (*select one*)

O CPAP
O BiPAP
O None

RVREG-011 Medical History

Peripheral Vascular Disease: **O** No **O** Yes **O** Unknown

*If **Yes***,

Asymptomatic: **O** No **O** Yes **O** Unknown

Symptomatic: **O** No **O** Yes **O** Unknown

Connective Tissue or Inflammatory Rheumatologic Disorder:

O No **O** Yes **O** Unknown

Neurological Event (stroke or TIA): **O** No **O** Yes **O** Unknown

---

Smoking History: **O** No **O** Yes **O** Unknown

*If **Yes**,* currently smoking? **O** No **O** Yes **O** Unknown

# of pack years _____ or **O** Unknown

*(**Pack Years** - The number of packs of cigarettes the subject smoked per day multiplied by the number of years. For example, a subject smoking 2 packs of cigarettes per day for 10 years would equal 20 pack years.)*

Psychiatric History: **O** No **O** Yes **O** Unknown

*If **Yes**,* hospitalization for major psychiatric illness?

O No **O** Yes **O** Unknown

RVREG-011 Medical History

Malnutrition: **O** No **O** Yes **O** Unknown

Significant (≥ 10 lbs) *unintentional* weight loss during the past year?
(i.e. not due to dieting or exercise): **O** No **O** Yes **O** Unknown

*If **Yes***, specify:

O ≥ 10 lbs and ≤ 20 lbs
O > 20 lbs and ≤ 40 lbs
O > 40 lbs

Is the subject on home oxygen? **O** No **O** Yes **O** Unknown

---

Was the patient on intravenous inotropes for other than diagnostic purposes in the last 90 days? **O** No **O** Yes

*If **Yes***, specify:

O 1 – 14 days
O 15 – 30 days
O 31 – 90 days

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-012 6 Minute Walk Test and 15 Feet Gait Speed Test

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

_____

Date of 6 Minute Walk Test and Gait Speed Test: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Person Performing Assessment: _____
(please print name clearly)

_____

Gait Speed Test

Gait Speed (15 feet walk time): _____ (seconds)

Was Gait Speed Test completed? **O** Yes **O** No

*If **No***, reason: (*select all that apply*)

❒ Chest pain
❒ Dizziness
❒ Severe dyspnea
❒ Other, specify:_____

_____

RVREG-012 6 Minute Walk Test and 15 Feet Gait Speed Test

6 Minute Walk Test

	Baseline	End of Test
Time (min:sec)	0:00	
Heart Rate (bpm)		
Systolic Blood Pressure (mmHg)		
Diastolic Blood Pressure (mmHg)		
Borg Dyspnea *(see MOP for Borg Scale)*		
Borg Fatigue *(see MOP for Borg Scale)*		

Stopped or paused before 6 minutes? **O** Yes **O** No

*If **Yes**,* reason: (*select all that apply*)

- ❒ Chest pain
- ❒ Dizziness
- ❒ Severe dyspnea
- ❒ Other, specify:_____

Was 6 Minute Walk Test completed? **O** Yes **O** No

*If **No***, reason: (*select all that apply*)

- ❒ Chest pain
- ❒ Dizziness
- ❒ Severe dyspnea
- ❒ Other, specify:_____

RVREG-012 6 Minute Walk Test and 15 Feet Gait Speed Test

Did the subject walk less than he/she would have walked otherwise due to orthopedic, arthralgic, or neurologic limitations?

O Yes **O** No

Total distance walked: _____ (meters)

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-013 Handgrip Strength Test

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

NOTE: *Make sure dynamometer is set at position 2 (2nd handle setting)*

Date of Handgrip Strength Test: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

What is the subject's dominant hand? **O** Right **O** Left
(this should be the hand used for the test)

Peak grip strength #1: __ __ __ lbs

Peak grip strength #2: __ __ __ lbs

Peak grip strength #3: __ __ __ lbs

NOTE: ***To be calculated by the DCC***

Peak grip strength **average**: __ __ __ lbs

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-014 ECG

O Baseline A **O** Baseline B
O Month 12

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed*:* _____

_____

NOTE*: If the heart failure subject has a historic ECG on file that was completed within 30 days of the assessment date, this may be used for fulfillment of this visit requirement if, in the opinion of the investigator, the historic ECG is highly likely to represent the subject's current health status.*

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Heart Rate (beats/min): __ __ __

Rhythm: (*select the one predominant rhythm*)
Atrial Rhythm:
- **O** Sinus Rhythm
- **O** Atrial Fibrillation
- **O** Atrial Flutter
- **O** Supraventricular tachycardia
- **O** Atrial pacing
- **O** Unknown
- **O** Other, specify: _____

RVREG-014 ECG

Atrioventricular conduction

PR duration (for subjects not in atrial fibrillation): _____ (msec)

2nd Degree Heart Block (Wenckebach, Mobitz Type I):	**O** Yes	**O** No
2nd Degree Heart Block (Mobitz Type II):	**O** Yes	**O** No
3rd Degree Heart Block (Complete Heart Block):	**O** Yes	**O** No

Intraventricular Conduction

Ventricular pacing:

Right ventricular pacing: **O** Yes **O** No

Left ventricular pacing: **O** Yes **O** No

NOTE: *If subject is receiving biventricular pacing, both right ventricular pacing and left ventricular pacing should be checked "Yes".*

Right Bundle Branch Block:	**O** Yes	**O** No	**O** Not applicable
Left Bundle Branch Block:	**O** Yes	**O** No	**O** Not applicable
Nonspecific IVCD:	**O** Yes	**O** No	**O** Not applicable

QRS Duration (msec): _____

Myocardial Infarction: **O** Acute **O** Old **O** NA

Subject ID: __ __ __ - __ __ __

RVREG-015 Seattle Heart Failure Model Score

O Baseline A **O** Baseline B
O Month 12

SHFM DATA WILL NOT BE COLLECTED IN THE OPENCLINICA DATABASE. ANALYSIS WILL BE COMPLETED BY DCC STATISTICAL STAFF AT THE END OF THE STUDY.

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

SHFM Score: _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-016 Initial Data

O Baseline A

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Length of time followed by study site's heart failure group:

O 0 – 3 months
O 3 – 12 months
O 1 – 2 years
O > 2 years

Prior heart transplant evaluation? **O** Yes **O** No

*If **Yes***, evaluation outcome:

O Reject (e.g., comorbidities, age, psychosocial)
O Defer (too well)
O Added

*If **Added***, listing date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Listing status:

O 1A
O 1B
O 2
O 7

O Unknown

Prior DT VAD evaluation? **O** Yes **O** No

*If **Yes***, evaluation outcome:

O Reject (e.g., comorbidities, age, psychosocial)
O Defer (too well)
O Accept

Resuscitation status:

O Full resuscitation
O DNR, DNI or both
O Unknown

Left Ventricular Ejection Fraction (%): __ __ . __

Ischemic etiology: **O** Yes **O** No

Devices: *(select one)*

O None
O ICD
O BiV Pacer
O BiV Pacer/ICD

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-017 Quality of Life Forms Tracking - Subject

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Date of Quality of Life Assessments: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Name of person administering Quality of Life Assessments:

_____
(please print name clearly)

Quality of Life Forms:

Instrument	Subject Completed?
EQ-5D (RVREG-018)	**O** Yes **O** No
Kansas City Cardiomyopathy Questionnaire (RVREG-019)	**O** Yes **O** No
PHQ-8 (RVREG-020)	**O** Yes **O** No
State Trait Anxiety Inventory (RVREG-021)	**O** Yes **O** No
VAD Survey (RVREG-022)	**O** Yes **O** No

RVREG-017 Quality of Life Forms Tracking - Subject

Select **One** response if any of the Instruments above were **Not Completed** by the **Subject** for the specific time period:

O subject states he or she is too sick to complete questionnaires

O coordinator did not approach subject because of health status

O subject refused, too tired

O subject refused, too stressed, anxious, and/or depressed

O subject refused, can't concentrate

O subject refused, no time/too busy

O subject refused, too much trouble/don't want to be bothered/not interested

O subject refused, no reason given

O subject missed a clinic appointment

O subject did not return mailed questionnaires

O subject unable to read English and/or is illiterate

O no time, coordinator too busy to administer questionnaires

O coordinator forgot to administer questionnaires

O subject dropped from study

O subject died

O other reason (describe): _____

Subject ID: __ __ __ - __ __ __

Method of Administration *(Select one):*
O patient self-report/clinic
O patient self-report/hospital
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Baseline A
O Month 6
O Month 18
O Baseline B
O Month 12
O Month 24

Health Questionnaire

(English version for the US)

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

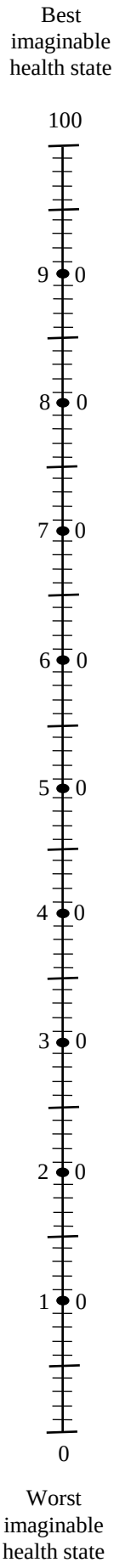
Subject ID: __ __ __ - __ __ __

Visit Date: __ __/__ __ __/__ __ __ __
DD MON YYYY

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked **100** and the worst state you can imagine is marked **0**.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Subject ID: __ __ __ - __ __ __

Visit Date: __ __/__ __ __/__ __ __ __
DD MON YYYY

REVIVAL Additional Questions
Please answer questions #1-6 below, so as to provide us with some additional information.

1. **Which of the following best describes your "<u>one" main activity</u>?**
   (select one)

Too sick to work (disabled)	**O**
Actively working	**O**
Keeping house	**O**
Student	**O**
Retired	**O**
Seeking work	**O**
Other	**O** Please specify:_____

   Is this "one" main activity considered:

   Full Time **O** ***or*** Part Time **O**

2. **How many of your close friends or relatives do you see in person, speak to on the telephone, or contact via the internet <u>at least once a month</u>? _____ (*please count each person 1 time*)**

<u>Please circle a number from 1 to 10 to respond to the questions below.</u>

3. **How much <u>stress</u> do you feel you've been under <u>during the past 1 month</u>, related to your health issues?**

1	2	3	4	5	6	7	8	9	10
No stress								Very much stress	

4. **How well do you feel you've been <u>coping</u> with or handling your stress <u>during the past 1 month</u>, related to your health issues?**

1	2	3	4	5	6	7	8	9	10
Coping very poorly								Coping very well	

5. How <u>confident</u> are you that you can do the tasks and activities needed to <u>manage your heart failure</u> so as to reduce how much having heart failure affects your everyday life?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

6. How satisfied are you with the <u>outcome</u> of your therapy for heart failure <u>during the past 6 months</u>?

1	2	3	4	5	6	7	8	9	10
Not satisfied									Very satisfied

Method of Administration: *(select one)*
O patient self-report/clinic
O patient self-report/hospital
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE

O Baseline A **O** Baseline B
O Month 6 **O** Month 12
O Month 18 **O** Month 24

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Heart Failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Place an **X** in one box on each line

Activity	Extremely limited	Quite a bit limited	Moderately limited	Slightly limited	Not at all limited	Limited for other reasons or did not do the activity
Dressing yourself	❒	❒	❒	❒	❒	❒
Showering/Bathing	❒	❒	❒	❒	❒	❒
Walking 1 block on level ground	❒	❒	❒	❒	❒	❒
Doing yardwork, housework or carrying groceries	❒	❒	❒	❒	❒	❒
Climbing a flight of stairs without stopping	❒	❒	❒	❒	❒	❒
Hurrying or jogging (as if to catch a bus)	❒	❒	❒	❒	❒	❒

2. Compared with 2 weeks ago, have your symptoms of **heart failure** (shortness of breath, fatigue or ankle swelling) changed? My symptoms of **heart failure** have become…

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
❒	❒	❒	❒	❒	❒

3. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in in the morning?

Every morning	3 or more times a week, but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
❒	❒	❒	❒	❒

4. Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been…

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
❒	❒	❒	❒	❒	❒

5. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you want?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
❒	❒	❒	❒	❒	❒	❒

6. Over the past 2 weeks, how much has your **fatigue** bothered you? It has been…

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
❒	❒	❒	❒	❒	❒

7. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
❒	❒	❒	❒	❒	❒	❒

8. Over the past 2 weeks, how much has your shortness of breath bothered you?

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
❒	❒	❒	❒	❒	❒

9. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every Night	3 or more times a week, but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
❒	❒	❒	❒	❒

10. Heart Failure symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
❒	❒	❒	❒	❒

11. How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse? (for example, weighing yourself, eating a low salt diet, etc.)

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
❒	❒	❒	❒	❒

12. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
❒	❒	❒	❒	❒

13. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
❒	❒	❒	❒	❒

14. Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
❒	❒	❒	❒	❒

15. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks?

Please place an **X** in one box on each line

Activity	**Severely** limited	Limited **quite a bit**	**Moderately** limited	**Slightly** limited	**Did not** limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities	❒	❒	❒	❒	❒	❒
Working or doing household chores	❒	❒	❒	❒	❒	❒
Visiting family or friends out of your home	❒	❒	❒	❒	❒	❒
Intimate relationships with loved ones	❒	❒	❒	❒	❒	❒

Developed by John Spertus et al., Mid America Heart Institute, Saint Luke's Hospital, Kansas City, MO.

Method of Administration: *(select one)*
O patient self-report/clinic
O patient self-report/hospital
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Baseline A **O** Baseline B
O Month 6 **O** Month 12
O Month 18 **O** Month 24

Patient

Personal Health Questionnaire

Over the past 2 weeks, how often have you been bothered by any of the following problems?

Please circle a number (0 to 3) for each question.

How often during the past 2 weeks were you bothered by...	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things?	0	1	2	3
2. Feeling down, depressed, or hopeless?	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much?	0	1	2	3
4. Feeling tired or having little energy?	0	1	2	3
5. Poor appetite or overeating?	0	1	2	3
6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down?	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television?	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual?	0	1	2	3

Kroenke K & Spitzer RL, (PHQ-8) 2002

Method of Administration (*Select one*):
O patient self-report/clinic
O patient self-report/hospital
O oral/interview

Subject ID: _____- _____

Visit Date: __ __/__ __ __/__ __ __ __
DD MON YYYY

SELF-EVALUATION QUESTIONNAIRE (STAI Form Y-1)

O Baseline A **O** Baseline B **O** Month 6
O Month 12 **O** Month 18 **O** Month 24

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment* . There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY	VERY MUCH SO
1. I feel calm……	1	2	3	4
2. I feel secure……	1	2	3	4
3. I feel tense……	1	2	3	4
4. I feel strained……	1	2	3	4
5. I feel at ease……	1	2	3	4
6. I feel upset……	1	2	3	4
7. I am presently worrying over possible misfortunes…..	1	2	3	4
8. I feel satisfied……	1	2	3	4
9. I feel frightened……	1	2	3	4
10. I feel comfortable……	1	2	3	4
11. I feel self-confident……	1	2	3	4
12. I feel nervous……	1	2	3	4
13. I am jittery……	1	2	3	4
14. I feel indecisive……	1	2	3	4
15. I am relaxed……	1	2	3	4
16. I feel content……	1	2	3	4
17. I am worried……	1	2	3	4
18. I feel confused……	1	2	3	4
19. I feel steady……	1	2	3	4
20. I feel pleasant……	1	2	3	4

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-022 VAD Survey

O Baseline A
O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Please read the following information

Heart failure develops when the heart is too weak to pump blood to the body. This can cause shortness of breath, tiredness and swelling. For most people, heart failure gets worse over time. Severe heart failure can even lead to death. Many effective medical treatments are available for heart failure, but sometimes medications alone are not enough.

Mechanical heart pumps called ventricular assist devices, or VADs, are a way to improve the blood flow throughout the body. These pumps do not replace the heart. They only assist the heart in pumping blood to the body. Presently, VADs are only used in patients with very advanced heart failure.

Placement of a VAD requires major open heart surgery. The pump is placed inside the chest and is connected to the heart. The VAD also has a power line that leaves the body through the skin in the front of the abdomen and is attached to a power supply outside the body.

On average, people will remain in the hospital for about two weeks after VAD surgery, sometimes longer. Patients and their caregivers attend education sessions to learn about how to use the new equipment. Once discharged from the hospital, most patients are able to return home and live independently.

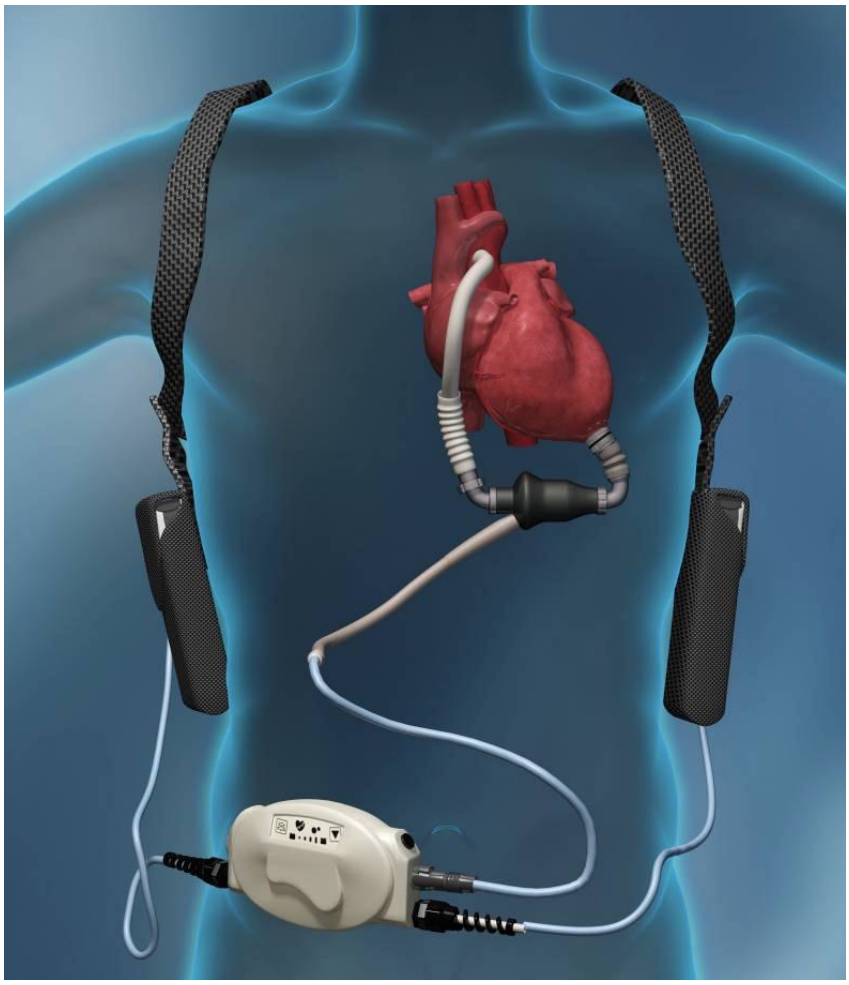
After 2 years, about 7 out of 10 patients who receive a VAD are still alive. Once recovered from surgery, most patients feel a big improvement in heart failure symptoms—less shortness of breath, more energy and less swelling.

RVREG-022 VAD Survey

Complications can occur after receiving a VAD. After 2 years, 7 in 10 patients will need to be readmitted to the hospital for complications.

- 1 in 10 will have a disabling stroke
- 2 in 10 will have a life threatening infection
- 3 in 10 will have bleeding from the stomach, bowels, or nose that requires a trip to the hospital
- 1 in 10 will need surgery to replace a VAD that is not working right

Illustration of a VAD:



RVREG-022 VAD Survey

Based on how you feel right now, how would you feel about having a VAD placed to treat your heart failure? *(select one)*

- **O** I would DEFINITELY want it
- **O** I would PROBABLY want it
- **O** I don't know if I would want it or not
- **O** I would PROBABLY NOT want it
- **O** I would DEFINITELY NOT want it

Based on how you feel today and what you know about your heart failure, what is your best guess of how much longer you have to live? For the purpose of this question, please assume that a VAD or a heart transplant would not be possible for you.

_____ Years

_____ Months

Many life-sustaining therapies are available near the end of life. These include dialysis, breathing machines, tubes for feeding, and heart resuscitation. Has your physician talked about your wishes regarding such life-sustaining therapies?

- **O** Yes
- **O** No

RVREG-022 VAD Survey

At this time, would you want any and all life-sustaining therapies available?

O Yes
O No

Are there any life-sustaining therapies you do not want?
(check all that apply)

❒ Kidney dialysis
❒ Being placed on a breathing machine
❒ Feeding tube if unable to eat
❒ Chest compressions
❒ Transfer to the Intensive Care Unit (ICU)

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-023 Heart Failure Survival Score

Baseline B

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

NOTE: This form will be completed by the DCC

DCC will be calculating and entering this score.
Form will be in OC but sites will not have access.

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Heart Failure Survival Score: _____

Heart Failure Survival Score Strata: _____

O Low
O Medium
O High

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-024 Sample Collection for Serum Analysis

Baseline B

Was the blood sample obtained? **O** Yes **O** No

*If **No**,* Reason sample not obtained:

_____

*If **Yes**,* Date Blood Sample Obtained: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Time Blood Sample Obtained: ____ ____ : ____ ____
HH:MM, 24-hour clock

NOTE: ***Blood samples will be shipped to the Biomarker Core Laboratory at the University of Pittsburgh: Director – Dennis McNamara***

Date of Shipment to Biomarker Core Laboratory: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

(please print clearly)

Person Shipping: _____

Email of Shipper: _____

Site Phone Number: _____
(XXX-XXX-XXXX)

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-024 Sample Collection for Serum Analysis

To be filled out by Core Lab/DCC:

Was sample for Serum Analysis received? **O** Yes **O** No

*If **No**,* Reason: _____

_____

*If **Yes**,* Date Shipment Received: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Name of Person Receiving Shipment: _____
(please print name clearly)

Additional comments: _____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-025 Sample Collection for RNA Analysis

Baseline B

Was the blood sample obtained? **O** Yes **O** No

*If **No**,* Reason sample not obtained:

_____

*If **Yes**,* Date Blood Sample Obtained: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Time Blood Sample Obtained: ____ ____ : ____ ____
HH:MM, 24-hour clock

NOTE: ***Blood samples will be shipped to the Biomarker Core Laboratory at the University of Pittsburgh: Director – Dennis McNamara***

Date of Shipment to Biomarker Core Laboratory: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

(please print clearly)

Person Shipping: _____

Email of Shipper: _____

Site Phone Number: _____
(XXX-XXX-XXXX)

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-025 Sample Collection for RNA Analysis

To be filled out by Core Lab/DCC:

Was sample for RNA Analysis received? **O** Yes **O** No

*If **No**,* Reason: _____

_____

*If **Yes**,* Date Shipment Received: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Name of Person Receiving Shipment: _____
(please print name clearly)

Additional comments: _____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-026 Sample Collection for Genomic DNA Analysis

Baseline B

Was the blood sample obtained? **O** Yes **O** No

*If **No**,* Reason sample not obtained:

_____

*If **Yes**,* Date Blood Sample Obtained: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Time Blood Sample Obtained: ____ ____ : ____ ____
HH:MM, 24-hour clock

NOTE: ***Blood samples will be shipped to the Biomarker Core Laboratory at the University of Pittsburgh: Director – Dennis McNamara***

Date of Shipment to Biomarker Core Laboratory: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

(please print clearly)

Person Shipping: _____

Email of Shipper: _____

Site Phone Number: _____
(XXX-XXX-XXXX)

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-026 Sample Collection for Genomic DNA Analysis

To be filled out by Core Lab/DCC:

Was sample for Genomic DNA Analysis received? **O** Yes **O** No

*If **No**,* Reason: _____

_____

*If **Yes**,* Date Shipment Received: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Name of Person Receiving Shipment: _____
(please print name clearly)

Additional comments: _____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD **MON** **YYYY**

RVREG-027 Cardiopulmonary Exercise Test Tracking

Baseline B

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

NOTE: ***Cardiopulmonary exercise test to be forwarded to the Cardiopulmonary Exercise Core Laboratory at Columbia University: Director – Donna Mancini, MD***

Date of Cardiopulmonary Exercise Test: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Was the gas calibration performed prior to subject testing? **O** Yes **O** No

Person Performing Test: _____
(*please print name clearly)*

Date submitted to DCC: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-027 Cardiopulmonary Exercise Test Tracking

Stage	Time (min)	HR	Systolic BP	Diastolic BP	BORG (RPE)
Rest	0				
1	3				
2	6				
3	9				
4	12				
5	15				
6	18				
7	21				
8	24				
9	27				
10	30				
Peak	____ : ____ (min:sec)				

REVIVAL

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-027 Cardiopulmonary Exercise Test Tracking

Data submitted in 30-second breath averages in tabular form:

(*all should be submitted*)

- ❒ VO_2 (mL/min)
- ❒ VCO_2 (mL/min)
- ❒ VE/ VO_2
- ❒ VE
- ❒ RR
- ❒ P_{ET} CO_2
- ❒ VO_2 (mL/kg/min)
- ❒ RER
- ❒ VE/ VCO_2
- ❒ HR
- ❒ P_{ET} O_2

Original color graphs submitted:

(*all should be submitted*)

- ❒ VO_2, VCO_2 vs Time
- ❒ P_{ET} CO_2, P_{ET} O_2 vs Time
- ❒ RER vs Time
- ❒ COMPOSITE ANAEROBIC THRESHOLD PLOT: VCO_2, P_{ET} O_2, VE/VO_2, RER VS VO_2
- ❒ VE/VO_2, VE/VCO_2 vs Time
- ❒ VCO_2 vs VO_2
- ❒ VE vs Time

Reason for stopping exercise:

(*select all that apply*)

- ❒ Dyspnea
- ❒ Chest Pain
- ❒ Dizziness
- ❒ Fatigue
- ❒ Claudication
- ❒ Other; specify_____
  _____

DCC use only:

Date Test Forwarded to Cardiopulmonary Exercise Core Laboratory:

__ __ /__ __ __ /__ __ __ __
DD MON YYYY

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-028 Cardiopulmonary Exercise Test

Baseline B

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

Entered by CPX Core Lab

Cardiopulmonary Exercise Test: _____ Month(s) post enrollment

Date of Assessment by Core Lab: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Cardiopulmonary Exercise Test Results:

Key Variables	Rest	Ventilatory Threshold	Peak Exercise
Time (min:sec)			
HR			
Mean arterial BP			
VE			
VE/VCO_2 @ AT			
RER			
VO_2 (mL/min)			
VO_2 (mL/kg/min)			
% Predicted VO_2			
Modified Borg Scale			
$P_{ET}CO_2$			
VO_2 pulse			

RVREG-028 Cardiopulmonary Exercise Test

Reason for stopping test: (*select all that apply*)

- ❒ Dyspnea
- ❒ Chest Pain
- ❒ Dizziness
- ❒ Fatigue
- ❒ Claudication
- ❒ Other; specify_____

Was the test a maximal CPX test? **O** Yes **O** No

Can you identify a significant non-cardiac component to the exercise limitation? **O** Yes **O** No

Comments: (*provide any additional explanation for test failure*)

_____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-029 Transthoracic Echocardiogram Tracking

Baseline B

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

NOTE: ***Echocardiogram to be forwarded to Echocardiogram Core Laboratory at the University of Pittsburgh: Director – John Gorcsan, MD***

Date of Transthoracic Echocardiogram: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Person Performing Transthoracic Echocardiogram:

_____
(*please print name clearly)*

Date submitted to DCC: **__ __ /__ __ __ /__ __ __ __**
DD MON YYYY

DCC use only:

Date Test Forwarded to Echocardiogram Core Laboratory:

__ __ /__ __ __ /__ __ __ __
DD MON YYYY

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-030 Transthoracic Echocardiogram

Baseline B

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

Entered by Echo Core Lab

Date of Transthoracic Echocardiogram: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Date of Assessment by Core Lab: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

LV Dimension (d)	_____	**(mm)**	**LVOT TVI**	_____	**(cm)**
LV Dimension (s)	_____	**(mm)**	**MV Peak E velocity**	_____	**(cm/s)**
LV fractional shortening	_____	**(%)**	**MV Deceleration Time**	_____	**(ms)**
Septal Thickness (d)	_____	**(mm)**	**MV Peak A velocity**	_____	**(cm/s)**
Posterior Wall Thickness (d)	_____	**(mm)**	**MV E/A**	_____	
LA Diameter (max)	_____	**(mm)**	**TDI E' Velocity (lateral)**	_____	**(cm/s)**
LVOT Diameter (s)	_____	**(mm)**	**Mitral E/E'**	_____	
LA Area (4-Chamber)	_____	**(cm^2)**			
RA Area (4-Chamber)	_____	**(cm^2)**			
LV Volumes and EF			**LV Short axis FAC:**		
End-Diastolic Volume (4-Ch)	_____	**(ml)**	**LV EDA**	_____	**(cm^2)**
End-Systolic Volume (4-Ch)	_____	**(ml)**	**LV ESA**	_____	**(cm^2)**
Ejection Fraction (4-Ch)	_____	**(%)**	**LV FAC**	_____	**(%)**
End-Diastolic Volume (2-Ch)	_____	**(ml)**	**LV EPPI**	_____	**(mmHg)**
End-Systolic Volume (2-Ch)	_____	**(ml)**	**Blood Pressure (Systolic)**	_____	**(mmHg)**

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-030 Transthoracic Echocardiogram

Ejection Fraction (2-Ch) _____ **(%)**

End-Diastolic Volume (Average) _____ **(ml)**

End-Systolic Volume (Average) _____ **(ml)**

Ejection Fraction (Average) _____ **(%)**

LV Apical Velocity (Inflow Cannula):

(systole) _____ **(m/sec)** **(diastole)** _____ **(m/sec)**

RV End-Diastolic Area	_____	**(cm^2)**	**TR Velocity (peak)**	_____	**(m/s)**
RV End-Systolic Area	_____	**(cm^2)**	**RA Pressure (estimate)**	_____	**(mmHg)**
RV Fractional Area Chg	_____	**(%)**	**PA Systolic Pressure**	_____	**(mmHg)**
TAPSE	_____	**(mm)**			

Mitral Regurgitation: O None/trace O Mild O Moderate O Mod-Severe O Severe

Mitral Regurgitation Vena Contracta: _____ **(mm)** **Mitral Regurgitant Jet Area:** _____ **(cm^2)**

Aortic Regurgitation: O None/trace O Mild O Moderate O Mod-Severe O Severe

Aortic Valve: O Closed O Intermitted O Opening normally

Tricuspid Regurgitation: O None/trace O Mild O Moderate O Mod-Severe O Severe

<u>LV Scar (Thin and Akinetic or Dyskinetic):</u>

Basal ❒ Anteroseptum ❒ Anterior ❒ Lateral ❒ Posterior ❒ Inferior ❒ Inferoseptum

Mid ❒ Anteroseptum ❒ Anterior ❒ Lateral ❒ Posterior ❒ Inferior ❒ Inferoseptum

Apical ❒ Septum ❒ Anterior ❒ Lateral ❒ Inferior

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-030 Transthoracic Echocardiogram

Feedback:

Echo Image Quality:	**O Excellent**	**O Good**	**O Unsatisfactory**
Protocol Compliance:	**O Excellent**	**O Good**	**O Unsatisfactory**

Left atrial thrombus present?	**O** Yes	**O** No
Left ventricular thrombus present?	**O** Yes	**O** No
Left ventricular end-diastolic dimension < 55 mm?	**O** Yes	**O** No
Calcification of the left ventricular apex?	**O** Yes	**O** No

COMMENTS: ***(if other significant clinical findings are found, provide below)***

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-031 Subject Follow-Up

O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24
O Early Termination

Was assessment completed? **O** Yes **O** No

*If **No,*** provide reason assessment was not completed: _____

_____

Date of Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Resuscitation status:

O Full resuscitation
O DNR, DNI or both
O Unknown

Has resuscitation status changed since the last visit? **O** Yes **O** No

*If **Yes***, provide date of status change: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Enrolled in hospice: **O** Yes **O** No **O** Unknown

*If **Yes***, enrollment date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-031 Subject Follow-Up

Has the subject transplant status been assessed <u>since the last visit</u>?

O Yes **O** No

*If **Yes,*** was the subject on the heart transplant list at the last visit?
O Yes **O** No

*If **Yes***, Evaluation outcome:

O Remained on the waiting list
O Removed from the waiting list because of worsening condition (e.g., comorbidities, age, psychosocial)
O Removed from the waiting list because of improved condition (i.e., alive without a transplant)
O Removed from the waiting list (transplanted or died)

*If **removed*** from the heart transplant waiting list, provide the most recent date of removal:

__ __ /__ __ __ /__ __ __ __
DD MON YYYY

*If **No***, Evaluation outcome:

O Reject (e.g., comorbidities, age, psychosocial)
O Defer (too well)
O Added

*If **added*** to the heart transplant waiting list, provide the first date of listing since the previous visit:
__ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-031 Subject Follow-Up

If the subject has not received a VAD or transplant since the last visit, has the subject been evaluated for VAD? **O** Yes **O** No

*If **Yes,*** provide the date of VAD evaluation:

__ __ __ /__ __ __ __ ***or*** **O** Unknown
MON YYYY

Evaluation outcome:

- **O** Approved and subject accepted
- **O** Approved but subject refused
- **O** Defer (too well)
- **O** Reject *(select all that apply)*
  - ❒ Comorbidities *(select all that apply)*
    - ❒ Renal function
    - ❒ Lung function
    - ❒ Liver function
    - ❒ Technical surgical issues
    - ❒ GI bleeding history
    - ❒ Infection
    - ❒ Neurological function *(select all that apply)*
      - ❒ Motor dysfunction
      - ❒ Cognitive dysfunction
      - ❒ Other
  - ❒ Age
  - ❒ Psychological
  - ❒ Absence of adequate social support
  - ❒ Other, specify: _____

RVREG-031 Subject Follow-Up

Has the subject had an assessment where the LVEF > 40% since the last visit?

O Yes
O No
O No LVEF assessment since last visit

Were there any hospitalizations since the last visit? **O** Yes **O** No

*If **Yes***, complete Hospitalization eCRF (RVREG-037) for each hospitalization

Did Caregiver complete the Quality of Life questionnaires at this visit?

O Yes **O** No

Has the subject been a resident of a rehabilitation facility since the last visit?

O Yes **O** No

*If **Yes***, provide number of days in a rehabilitation facility since the last visit: _____

Has the subject been a resident of a long-term care facility or nursing home since the last visit? **O** Yes **O** No

*If **Yes***, provide number of days in a long-term care facility or nursing home since the last visit: _____

RVREG-031 Subject Follow-Up

The following questions are to be completed at Baseline B and Month 12 ONLY:

Ischemic etiology: **O** Yes **O** No

Devices: *(select one)*

- **O** None
- **O** ICD
- **O** BiV Pacer
- **O** BiV Pacer/ICD

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-032 Documentation of Informed Consent - Caregiver

Baseline B

Did the Caregiver sign the Caregiver Informed Consent:

O Yes **O** No

*If **Yes***, date Caregiver consent was signed:

__ __ /__ __ __ /__ __ __ __
DD MON YYYY

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD **MON** **YYYY**

RVREG-033 Quality of Life Forms Tracking - CAREGIVER

O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Date of Quality of Life Assessment: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Name of Person administering Quality of Life Assessment:

_____
(please print name clearly)

Quality of Life Forms:

Instrument	Caregiver Completed?
Caregiver Health History (RVREG-034a) *Baseline B visit only*	**O** Yes **O** No **O** Not applicable
Caregiver Health History (RVREG-034b) *Follow-up visits only*	**O** Yes **O** No **O** Not applicable
Caregiver EQ-5D (RVREG- 035)	**O** Yes **O** No
Oberst Caregiver Burden Scale (RVREG- 036)	**O** Yes **O** No

RVREG-033 Quality of Life Forms Tracking - CAREGIVER

Select **One** response if any of the Instruments above were **Not Completed** by the **Caregiver** for the specific time period:

O caregiver states he or she is too sick to complete questionnaires

O coordinator did not approach caregiver because of health status

O caregiver refused, too tired

O caregiver refused, too stressed, anxious, and/or depressed

O caregiver refused, can't concentrate

O caregiver refused, no time/too busy

O caregiver refused, too much trouble/don't want to be bothered/not interested

O caregiver refused, no reason given

O caregiver did not attend a clinic visit

O caregiver did not return mailed questionnaires

O caregiver unable to read English and/or is illiterate

O no time, coordinator too busy to administer questionnaires

O coordinator forgot to administer questionnaires

O subject dropped from study

O subject died

O caregiver dropped from study

O caregiver died

O other reason (describe): _____

Subject ID: __ __ __ - __ __ __

Method of Administration: *(select one)*
O self-report/clinic
O self-report/home
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Baseline B

Caregiver Health History

Caregiver's Contact Information:

First Name: _____

Last Name: _____

Mailing Address: _____

City: _____

State (*abbreviation*): __ __ Zip: __ __ __ __ __

Home phone #: _____ Work phone #: _____
(XXX-XXX-XXXX) (XXX-XXX-XXXX)

Relationship to subject: *(please select one)*
O Spouse/Domestic Partner
O Son/Daughter
O Other family member (describe) _____
O Friend
O Other (describe) _____

Date of Birth: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Gender: **O** Male **O** Female

Ethnicity:

- **O** Hispanic or Latino
- **O** Non-Hispanic or Non-Latino
- **O** Unknown/Undisclosed

Race: *(please select all that apply)*

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

Select your highest educational level:

- **O** Less than high school
- **O** Some high school
- **O** High school graduate
- **O** Some college or specialized training
- **O** College or university graduate
- **O** Post graduate training or degree

Do you have any children?

- **O** Yes *If **Yes**,* how many children: _____
- **O** No

Select your current marital status:

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

Do you live in the same house as the subject for whom you are a Caregiver?

- **O** Yes
- **O** No

Are you working for income?

- **O** Yes — *If **Yes**,* select: **O** part-time ***or*** **O** full-time
- **O** No
- **O** Unknown

Past Medical History: Select all that apply *regarding medical conditions that you <u>have now or have had in the past</u>*.

- ❒ Heart failure
- ❒ Heart attack
- ❒ Coronary artery disease
- ❒ Other heart disease (describe) _____
- ❒ Stroke
- ❒ Hypertension (high blood pressure)
- ❒ Aneurysm
- ❒ Diabetes
- ❒ Blood disorder
- ❒ Kidney disease
- ❒ Peripheral vascular disease
- ❒ High cholesterol
- ❒ Liver disease
- ❒ Autoimmune disease
- ❒ Arthritis
- ❒ Lung disease
- ❒ Thyroid disease
- ❒ Nervous system disorder
- ❒ Psychiatric disorder
- ❒ Seizures
- ❒ Skin or muscle disease
- ❒ Gout
- ❒ Bone disease
- ❒ Cancer (describe) _____
- ❒ Disease of eyes, ears, nose, throat (describe) _____
- ❒ Disease of stomach, intestines, colon (describe) _____
- ❒ Other (describe) _____ _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ ___ __ __
DD MON YYYY

Past Surgical History: Number of surgeries: _____

Please list <u>all</u> previous surgeries:

Surgery

Please circle a number below to indicate whether you think that your health will be affected by being a Caregiver for a subject participating in this Registry:

1 2 3 4 5 6 7 8 9 10

Health will worsen — Health will remain the same or improve

Thank you!

Subject ID: __ __ __ - __ __ __

Method of Administration: *(select one)*
O self-report/clinic
O self-report/home
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Month 6 **O** Month 12
O Month 18 **O** Month 24

Caregiver Health History

Select your highest educational level:

- **O** Less than high school
- **O** Some high school
- **O** High school graduate
- **O** Some college or specialized training
- **O** College or university graduate
- **O** Post graduate training or degree

Do you have any children?

- **O** Yes *If **Yes**,* how many children: _____
- **O** No

Select your current marital status:

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

Do you live in the same house as the subject for whom you are a Caregiver?

- **O** Yes
- **O** No

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ ___ __ __
DD MON YYYY

Are you working for income?

O Yes *If **Yes**,* select: **O** part-time ***or*** **O** full-time
O No
O Unknown

Past Medical History: *Select <u>all</u> medical conditions that you are experiencing or have experienced since the last time you completed this form:*

❒ Heart failure
❒ Heart attack
❒ Coronary artery disease
❒ Other heart disease (describe) _____
❒ Stroke
❒ Hypertension (high blood pressure)
❒ Aneurysm
❒ Diabetes
❒ Blood disorder
❒ Kidney disease
❒ Peripheral vascular disease
❒ High cholesterol
❒ Liver disease
❒ Autoimmune disease
❒ Arthritis
❒ Lung disease
❒ Thyroid disease
❒ Nervous system disorder
❒ Psychiatric disorder
❒ Seizures
❒ Skin or muscle disease
❒ Gout
❒ Bone disease
❒ Cancer (describe) _____
❒ Disease of eyes, ears, nose, throat (describe) _____
❒ Disease of stomach, intestines, colon (describe) _____
❒ Other (describe) _____
_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ ___ __ __
DD MON YYYY

Surgical History: Please list <u>all</u> surgeries performed on you since the last time you completed this form.

Number of surgeries since the last time you completed this form: _____

Surgery

Please circle a number below to indicate whether you think that your health will be affected by being a Caregiver for a subject participating in this Registry:

1 2 3 4 5 6 7 8 9 10

Health will worsen — Health will remain the same or improve

Thank you!

Subject ID: __ __ __ - __ __ __

Method of Administration: *(select one)*
O self-report/clinic
O self-report/home
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

Health Questionnaire
For Caregivers

(English version for the US)

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

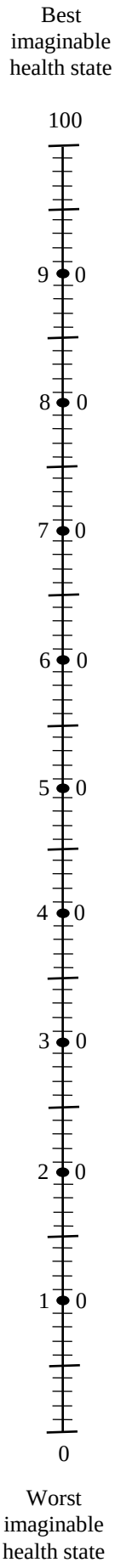
Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked **100** and the worst state you can imagine is marked **0**.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Method of Administration: *(select one)*
O self-report/clinic
O self-report/home
O oral/interview

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Baseline B
O Month 6
O Month 12
O Month 18
O Month 24

OBERST CAREGIVING SCALE

This group of questions is about the tasks and activities that you do as a caregiver for a patient who has moderately advanced heart failure. For each of the following activities, please mark how much time you spend and how difficult each activity is for you to do.

1. Medical or nursing treatments (giving medications, skin care, dressings, etc.)

____ A great amount
____ A large amount
____ A moderate amount
____ A small amount
____ None

____ Extremely difficult
____ Very difficult
____ Moderately difficult
____ Slightly difficult
____ Not difficult

2. Personal care (bathing, toileting, getting dressed, feeding, etc.):

____ A great amount
____ A large amount
____ A moderate amount
____ A small amount
____ None

____ Extremely difficult
____ Very difficult
____ Moderately difficult
____ Slightly difficult
____ Not difficult

3. Assistance with walking, getting in and out of bed, exercises, etc.:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

4. Emotional support, "being there" for the patient:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

5. Watching for and reporting the patient's symptoms, watching how the patient is doing, monitoring the patient's progress:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

6. Providing transportation or "company" (driving, riding along with patient, going to appointments, driving patient around for errands, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

7. Managing finances, bills, and forms related to the patient's illness:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

8. Additional household tasks for the patient (laundry, cooking, cleaning, yard work, home repairs, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

9. Additional tasks outside the home for the patient (shopping for food and clothes, going to the bank, running errands, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

10. Structuring/planning activities for the patient (recreation, rest, meals, things for the patient to do, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

11. Managing behavior problems (moodiness, irritability, confusion, memory loss, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

12. Finding and arranging someone to care for the patient while you are away:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

13. Communication (helping the patient with the phone, writing or reading, explaining things, trying to understand what the patient is trying to say, etc.):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

14. Coordinating, arranging, and managing services and resources for the patient (scheduling appointments, arranging transportation, locating equipment and services, and finding outside help):

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

15. Seeking information and talking with doctors, nurses, and other professional health care workers about the patient's condition and treatment plans:

____ A great amount	____ Extremely difficult
____ A large amount	____ Very difficult
____ A moderate amount	____ Moderately difficult
____ A small amount	____ Slightly difficult
____ None	____ Not difficult

Oberst Caregiving Burden Scale (OCBS), Indiana University School of Nursing, 1989

RVREG-037 Hospitalization

Hospitalization

NOTE: ***Complete this form at the time of the subject's discharge to ensure the most accurate reason(s) for hospital admission.***

Date of Hospital Admission: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Date of Hospital Discharge: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

NOTE: ***If subject died during this hospitalization, provide death date as hospital discharge date and complete Death eCRF, RVREG-041.***

Number of Intensive Care Unit days during this hospital admission: _____

What was the <u>one main reason</u> for hospitalization:

O Cardiovascular

O Cardiac

O Heart failure related

Was this a **<u>planned</u>** admission for a heart failure procedure or device (RHC, ICD, CRT, or CRT-D, but not transplant or VAD)? **O** Yes **O** No

O ST elevation myocardial infarction

O NSTEMI/acute coronary syndrome

O Planned coronary angiography or intervention (PCI or CABG)

O Arrhythmic event

- **O** Planned, non-heart failure-related, arrhythmia treatment (e.g., Afib/flutter/VT/AV node ablation, single or dual chamber pacemaker, elective cardioversion)
- **O** Syncope (without identified arrhythmia as the cause)
- **O** Complication of cardiac medication or procedure
- **O** Other – Cardiac, specify: _____

O Neurovascular

- **O** Stroke

  Date of Stroke: __ __ /__ __ __ /__ __ __ __
  DD MON YYYY

- **O** TIA

O Venous thromboembolic disease

- **O** Pulmonary embolism
- **O** DVT

O Other vascular

- **O** Aortic aneurysm
- **O** Aortic dissection
- **O** Non-CNS arterial embolic disease
- **O** Other peripheral arterial disease
- **O** Other peripheral venous disease

- **O** Noncardiovascular
  - **O** Renal
  - **O** Electrolyte disturbance
  - **O** Pulmonary
    - **O** Pneumonia
    - **O** Other pulmonary
  - **O** Hepatic
  - **O** Major bleeding
  - **O** GI disorder (other than bleeding)
  - **O** Infection (other than pneumonia)
  - **O** Fever treated with antibiotics without known cause
  - **O** Psychiatric episode
  - **O** Neurological event (excluding stroke or TIA)
  - **O** Trauma or accident
  - **O** Noncardiac elective surgery (e.g., joint replacement, GU or GYN surgery)
  - **O** Other

RVREG-037 Hospitalization

What interventions were performed during this hospitalization?
(check all that apply)

❒ Diagnostic (*check all that apply*)

❒ Right Heart Catheterization

❒ Left Heart Catheterization/Coronary Angiography

❒ Therapeutic (*check all that apply*)

❒ Heart Failure (*check all that apply*)

❒ Inotropes

First date of inotrope use during this hospitalization:

__ __ /__ __ __ /__ __ __ __
DD MON YYYY

Was the subject on continuous inotropes at the time of the first of the following events: discharge, mechanical circulatory support, transplant, or death? **O** Yes **O** No

Was the subject inotrope-dependent at the time of the first of the following events: discharge, mechanical circulatory support, transplant, or death? **O** Yes **O** No

❒ Temporary MCS (provide **ALL** temporary MCS for this hospitalization)

	Temporary MCS Type	**Implant Date DD/MON/YYYY**
#1	**O** IABP **O** temporary LVAD **O** temporary RVAD **O** ECMO	__ __ /__ __ __ /__ __ __ __

#2	**O** IABP **O** temporary LVAD **O** temporary RVAD **O** ECMO	__ __ /__ __ __ /__ __ __ __
#3	**O** IABP **O** temporary LVAD **O** temporary RVAD **O** ECMO	__ __ /__ __ __ /__ __ __ __
#4	**O** IABP **O** temporary LVAD **O** temporary RVAD **O** ECMO	__ __ /__ __ __ /__ __ __ __
#5	**O** IABP **O** temporary LVAD **O** temporary RVAD **O** ECMO	__ __ /__ __ __ /__ __ __ __

❒ Durable ventricular assist device: (*check all that apply*)

❒ Durable implantable LVAD

Implant Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

❒ Durable implantable RVAD

Implant Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

❒ TAH

Implant Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

❒ C-Pulse heart assist system

❒ Heart transplant

Date of heart transplant: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-037 Hospitalization

Listing status at heart transplant:

- **O** 1A
- **O** 1B
- **O** 2

❒ Arrhythmia (*check all that apply*)

- ❒ Pacemaker (single or dual chamber)
- ❒ CRT (biventricular pacemaker)
- ❒ CRT-D (biventricular pacemaker with ICD)
- ❒ ICD alone
- ❒ Atrial arrhythmia or AV node ablation
- ❒ Ventricular arrhythmia ablation
- ❒ Cardioversion/Defibrillation
  - **O** Elective (hemodynamically stable)
  - **O** Nonelective (nonhemodynamically stable)

❒ Coronary (*check all that apply*)

- ❒ Percutaneous Coronary Intervention (PCI)
- ❒ CABG

❒ Valvular (*check all that apply*)

- ❒ Aortic valve surgery (repair or replacement)
- ❒ Mitral valve surgery (repair or replacement)
- ❒ Tricuspid valve surgery (repair or replacement)
- ❒ Percutaneous mitral valve procedure
- ❒ TAVR

RVREG-037 Hospitalization

❒ Other (*check all that apply*)

- ❒ IV antibiotics
- ❒ Blood transfusion
- ❒ Endoscopy (upper or lower or capsule)
- ❒ Hemodialysis
- ❒ Ultrafiltration/Aquapheresis only (no dialysis)
- ❒ Intubation/mechanical ventilation

❒ Other surgical or percutaneous procedures or interventions (*provide below*)

1. _____
2. _____
3. _____
4. _____
5. _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-038 Adverse Event - Subject

Adverse Event

Note: ***This form is ONLY completed for Adverse Events resulting from <u>research-related procedures</u> incurred during the course of the Registry.***

Adverse Event Term: _____

Major Organ System involved with Adverse Event: *(select one)*

- **O** Nervous
- **O** Respiratory
- **O** Cardiovascular
- **O** Digestive
- **O** Endocrine
- **O** Reproductive
- **O** Renal
- **O** Urologic
- **O** Hematological
- **O** Orthopedic
- **O** Musculoskeletal
- **O** Immune/Lymphatic
- **O** Integumentary
- **O** Psychiatric
- **O** Other, *specify* _____

Date of Onset: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Did the Adverse Event occur during or after any study-related procedure or test? (e.g., cardiopulmonary exercise test, 6 minute walk test, echocardiogram)

O Yes **O** No

***If Yes,* relationship to procedure or test:**

O Probable **O** Possible **O** Unlikely

RVREG-038 Adverse Event - Subject

Location of the subject at time of onset of the Adverse Event:

- **O** Outpatient facility
- **O** Hospital
- **O** Home
- **O** Nursing home or rehabilitation center
- **O** Other, specify: _____

Is this a Serious AE? **O** Yes **O** No

If a Serious Adverse Event: *(check all that apply)*

- ❒ Death
- ❒ Life-threatening
- ❒ Hospitalization
- ❒ Prolongation of hospitalization
- ❒ Resulted in significant or persistent disability
- ❒ Resulted in congenital anomaly/birth defect
- ❒ Other Serious (important medical events)

Expectedness: **O** Expected **O** Unexpected

Event Outcome:

- **O** Ongoing
- **O** Resolved

  Date: __ __ /__ __ __ /__ __ __ __
  DD MON YYYY

- **O** Resolved with sequelae

  Date: __ __ /__ __ __ /__ __ __ __
  DD MON YYYY

- **O** Death [*complete Death eCRF (RVREG-041)* ***and*** *Final Status – Subject eCRF (RVREG-042)*]

RVREG-038 Adverse Event - Subject

*If **Death**,* did this Adverse Event contribute to death?

O Yes **O** No **O** Unknown

Did this Adverse Event result in a diagnostic or therapeutic procedure or surgical intervention? **O** Yes **O** No

*If **Yes**,* provide procedure or surgical intervention name(s):

_____

_____

_____

Brief Narrative of Event: _____

_____

_____

_____

_____

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-039 Adverse Event - Caregiver

Adverse Event

Note: ***This form is ONLY completed for Adverse Events resulting from <u>research-related procedures</u> incurred during the course of the Registry.***

Adverse Event Term: _____

Major Organ System involved with Adverse Event: *(select one)*

- **O** Nervous
- **O** Respiratory
- **O** Cardiovascular
- **O** Digestive
- **O** Endocrine
- **O** Reproductive
- **O** Renal
- **O** Urologic
- **O** Hematological
- **O** Orthopedic
- **O** Musculoskeletal
- **O** Immune/Lymphatic
- **O** Integumentary
- **O** Psychiatric
- **O** Other, *specify* _____

Date of Onset: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Did the Caregiver Adverse Event occur during or after any study-related questionnaire was completed? (e.g., psychological distress)

O Yes **O** No

*If **Yes,*** relationship to study assessment:

O Probable **O** Possible **O** Unlikely

RVREG-039 Adverse Event - Caregiver

Is this a Serious AE? **O** Yes **O** No

If a Serious Adverse Event: *(check all that apply)*

- ❒ Death
- ❒ Life-threatening
- ❒ Hospitalization
- ❒ Prolongation of Hospitalization
- ❒ Resulted in significant or persistent disability
- ❒ Resulted in congenital anomaly/birth defect
- ❒ Other Serious (important medical events)

Expectedness: **O** Expected **O** Unexpected

Event Outcome:

O Ongoing

O Resolved

Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Resolved with sequelae

Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

O Death (*complete Final Status – Caregiver eCRF (RVREG-043)*

If ***Death,*** did this Adverse Event contribute to death?
O Yes **O** No **O** Unknown

O Unknown

RVREG-039 Adverse Event - Caregiver

Did this Adverse Event result in a diagnostic or therapeutic procedure or surgical intervention? **O** Yes **O** No

*If **Yes**,* provide procedure or surgical intervention name(s):

_____

_____

_____

Continue participation in the Registry? **O** Yes **O** No

Brief Narrative of Event: _____

_____

_____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-040 Protocol Deviation

Protocol Deviation

Date Deviation Occurred: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Date Deviation Reported: __ __ /__ __ __ /__ __ __ __
DD MON YYYY
(either date called in or date entered in eCRF)

Deviation reported by: _____
(please print name clearly)

Deviation Details: *(select one)*
- **O** Study visit schedule deviation
- **O** Confidentiality breach
- **O** Protocol procedure deviation (*select all that apply*)
  - ❒ 6 minute walk test not done
  - ❒ Gait speed test not done
  - ❒ Blood draw not done
  - ❒ Quality of Life questionnaire not completed
  - ❒ ECG not done
  - ❒ Handgrip strength test not done
  - ❒ CPX test not done
  - ❒ Echocardiogram not done
- **O** Informed consent deviation
- **O** Subject was enrolled into study but was ineligible
- **O** Other; specify: _____

Reason for Deviation: *(select primary reason for deviation)*
- **O** Subject missed appointment *(specify visit)*
- **O** Visit completed outside protocol-specified window *(specify visit)*
- **O** Subject refused
- **O** Clinical site error
- **O** Adverse Event

RVREG-040 Protocol Deviation

O Other, specify: _____

Specify visit if missed appointment or completed outside protocol-specified window: *(select one)*

- **O** Baseline A
- **O** Baseline B
- **O** Month 6
- **O** Month 12
- **O** Month 18
- **O** Month 24

Was the IRB notified of the Protocol Deviation:

O Yes **O** No

*If **Yes***, date of notification to the IRB: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

*If **No***, specify reason:

- **O** Not required per IRB policy
- **O** To be reported at annual continuing review

Provide a short narrative of the protocol deviation:

_____

_____

_____

_____

RVREG-041 Death

Death

Date of Death: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

DNR or DNI or both in place at time of death?
- **O** Yes
- **O** No
- **O** Unknown

Enrolled in hospice at time of death?
- **O** Yes
- **O** No
- **O** Unknown

Location of death:
- **O** Hospital
- **O** Out of hospital
- **O** Unknown

Expectedness of death:
- **O** Expected
- **O** Unexpected
- **O** Unknown

What was the Primary Cause of death: The primary cause of death refers to the disease or injury that **initiated** the train of terminal events leading directly to death. Select **one** primary cause of death from the list below:

- **O Cardiac**
  - **O** Heart Failure
  - **O** Myocardial Infarction
  - **O** Sudden Death
  - **O** Other, specify: _____

O Cerebrovascular
O Other Vascular
O Cancer
O Infection
O Kidney Failure
O Liver Failure
O Pulmonary Embolism
O Respiratory Failure
O Other, *specify*: _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-042 Final Status - Subject

Final Status

Last day in study: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Did subject complete the Registry through Month 24: **O** Yes **O** No

If **No**, please indicate ***primary*** reason for discontinuation:

- **O** Subject withdrew consent, no Month 24 follow-up
- **O** Investigator withdrawal, no Month 24 follow-up
- **O** Adverse Event

  (*If Adverse Event was **related to a research procedure**, complete Adverse Event - Subject eCRF, RVREG-038)*

- **O** Lost to follow-up

  Last known date alive: __ __ /__ __ __ /__ __ __ __
  DD MON YYYY

- **O** Subject received a heart transplant
- **O** Subject received a durable implantable VAD
- **O** Death (*complete Death eCRF, RVREG-041*)
- **O** Study termination
- **O** Other, specify: _____
  _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-043 Final Status - Caregiver

Final Status

Last day in study: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Did Caregiver complete the Registry through Month 24: **O** Yes **O** No

If No, please indicate ***primary*** reason for not completing:

O Caregiver withdrew consent

O Subject early termination

O Caregiver death

O Study termination

O Other, specify _____

Comments: _____

_____

_____

_____

_____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-044 Subject Visit Termination (withdrawal)

Early Termination

NOTE: *Complete this form ONLY if subject withdrew consent, subject was withdrawn by Investigator, or if a procedure-related Adverse Event was the reason for early termination. An Adverse Event would qualify for either of the two categories listed below.*

Effective date of visit termination: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Reason for visit termination: (*select one*)

- **O** Subject withdrew consent
  - **O** Subject is willing to provide outcome data at Month 24
    [complete Subject Follow-Up eCRF (RVREG-031) at the time of the visit termination; also complete Hospitalization eCRF (RVREG-037) and Adverse Event – Subject eCRF (RVREG-038) if applicable]
  - **O** Subject is NOT willing to provide outcome data at Month 24
    (complete Final Status – Subject eCRF (RVREG-042)
- **O** Investigator withdrawal
  - **O** Subject is willing to provide outcome data at Month 24
    [complete Subject Follow-Up eCRF (RVREG-031) at the time of the visit termination; also complete Hospitalization eCRF (RVREG-037) and Adverse Event – Subject eCRF (RVREG-038) if applicable]
  - **O** Subject is NOT willing to provide outcome data at Month 24
    (complete Final Status – Subject eCRF (RVREG-042)
- **O** Other, specify: _____

Subject ID: __ __ __ - __ __ __

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-045 Final Status for Withdrawn Subject

Final Status

This form is <u>ONLY</u> to be completed for subjects who have withdrawn from the study <u>AND</u> who have agreed to provide study outcomes data at Month 24. <u>This data should reflect subject status exactly 24 months (730 days) from the informed consent date. However, just as for patients who did not withdraw from the study, enter only the FIRST event (transplant, LVAD, or death). Events occurring after the first event should not be recorded on this form .</u>

Was outcomes data obtained: **O** Yes **O** No

*If **No,*** provide reason: _____

_____

Date of contact with subject: __ __ /__ __ __ /__ __ __ __ ***or*** **O** Not applicable
DD MON YYYY

Since date of subject withdrawal, which of the following occurred <u>FIRST</u>:
(select only one)

O Subject received a heart transplant

Date of transplant: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Listing status at heart transplant:

O 1A
O 1B
O 2
O Unknown

O Subject received a durable implantable VAD

RVREG-045 Final Status for Withdrawn Subject

Date of implant: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

INTERMACS Patient Profile at time of implant:

- **O** INTERMACS 1
- **O** INTERMACS 2
- **O** INTERMACS 3
- **O** INTERMACS 4
- **O** INTERMACS 5
- **O** INTERMACS 6
- **O** INTERMACS 7
- **O** Unknown

INTERMACS® Modifier Present: **O** No **O** Yes

*If **Yes**, check all that apply:*

- ❑ A - Arrhythmia. This modifier can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to the overall clinical course. This includes frequent shocks from ICD or requirement for external defibrillator, usually more than twice weekly.

- ❑ TCS –Temporary Circulatory Support. This modifier can modify only patients who are confined to the hospital, Patient Profiles 1, 2, and 3 (a patient who is listed as Patient Profile 3 stable on inotropes who has been at home until elective admission for implantable VAD cannot have a TCS modifier.) Support includes IABP, ECMO, TandemHeart, Levitronix, BVS 5000 or AB5000, Impella.

RVREG-045 Final Status for Withdrawn Subject

- ❑ FF – Frequent Flyer. This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. NOTE: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

O Death

Date of death: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

Was the subject receiving continuous IV inotropes at the time of death: **O** Yes **O** No **O** Unknown

O None of the above

If none of the above was met, complete the following at Month 24 *(730 days from informed consent date)*:

O Subject is alive

Is the subject receiving continuous IV inotropes:
O Yes **O** No **O** Unknown

O Unable to obtain information

RVREG-045 Final Status for Withdrawn Subject

Explain: _____

_____

_____

Visit Date: __ __ /__ __ __ /__ __ __ __
DD MON YYYY

RVREG-046 Listing at VAD

VAD Listing

NOTE: ***This form should ONLY be completed for subjects who receive a durable VAD implant.***

Was this subject listed for a heart transplant at the time of their durable VAD implant?

O Yes **O** No