**Short-Term or Temporary Mechanical Circulatory Support (MCS) Module:**

**Data Elements to Collect**

*Mechanical Ventilation*

Yes

No

*Renal Replacement Therapy (if yes, specify)*

Yes

Ultrafiltration

CVVH

Intermittent hemodialysis

Other

No

**Previous Temporary MCS Devices Removed During Current Hospitalization**

Yes

No

*If yes, specify type(s) of primary temporary MCS and dates of implant/removal:*

Intra-aortic balloon pump (Implant date: Explant date: )

ECMO (Implant date: Explant date: )

Percutaneous micro axial pump (Implant date: Explant date: )

Other (specify) (Implant date: Explant date: )

**Current Temporary MCS Devices**

Yes

No

*If yes, specify type(s) of current temporary MCS and dates of implant:*

Intra-aortic balloon pump (Implant date: )

ECMO (Implant date: )

Percutaneous micro axial pump (Implant date: )

Other (specify) (Implant date: )

Current Temporary MCS Device Setting (specify):

**Additional Patient Characteristics to Capture**

INTERMACS Patient Profile (specify 1 – 7) \_\_\_\_\_\_\_\_\_\_\_\_

Duration at current INTERMACS Patient Profile (days) \_\_\_\_\_\_\_\_\_\_

*If subject is not a transplant candidate, indicate reason(s):*

Age

Diabetes Mellitus

Obesity

Chronic kidney disease

Pulmonary hypertension

Pulmonary disease (such as COPD)

Cancer

Psychological considerations (compliance, substance abuse)

Allosensitization/High Panel Reactive Antibody (PRA) level

Patient choice

Prior Cardiac Surgery

Yes

No

*If yes, specify prior cardiac surgery:*

Type of surgery:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surgical approach:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of prior median sternotomies:\_\_\_\_\_\_\_\_\_\_\_\_\_

History of Hypercoagulable Disorder (eg. APLAS, unprovoked PE/DVT)

Yes

No

History of Heparin Induced Thrombocytopenia:

Yes

No

**Additional Lab Values to Capture at Baseline:** (Some labs, from baseline CRF plus additional values, may need to be collected at multiple time points after temporary MCS implant, e.g., renal function, LDH, Hb)

1. ABO Blood Type: \_\_\_\_\_\_\_\_\_
2. Albumin: \_\_\_\_\_\_\_\_\_\_
3. Total Bilirubin: \_\_\_\_\_\_\_\_
4. Serum alanine aminotransferase (ALT): \_\_\_\_\_\_\_\_\_\_\_\_
5. International normalized ration (INR): \_\_\_\_\_\_\_\_\_
6. Total Cholesterol:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. Platelet Count:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
8. Lymphocyte Percentage:\_\_\_\_\_\_\_\_\_\_
9. Uric Acid:\_\_\_\_\_\_\_\_\_\_\_
10. LDH:\_\_\_\_\_\_\_\_\_\_\_
11. Plasma Free Hemoglobin:\_\_\_\_\_\_\_\_\_\_\_\_\_

**Temporary MCS Implantation CRF Elements:**

Type/serial number of device:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Ventricle Supported:*

Left ventricle support

Right ventricle support

Biventricular support

Implant Date/Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Implant Site (specify vascular access):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Implant positioning confirmed by (select all that apply):*

Fluoroscopy/X-ray

Echocardiography

Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the device successfully implanted?

Yes

No

*If no, reason for unsuccessful attempt (select all that apply):*

Device malfunction

Failed access

Failed deliver

Failed positioning of device during the procedure

Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Temporary MCS device settings:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did any intra-procedural complications occur?

Yes (if yes, specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

*Antiplatelet*

Yes (if yes, specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

*Anticoagulant*

Yes (if yes, specify anticoagulant and PTT goal):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

Implant Indication:

*Cardiogenic shock*

Yes

No

*If yes, specify type(s) of current temporary MCS and dates of implant:*

Acute myocardial infarction

Post-cardiac arrest

Post-cardiotomy shock (after open heart surgery), specify procedure:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Acute heart failure/new onset cardiomyopathy (e.g., myocarditis)

Chronic heart failure/chronic cardiomyopathy

Other form of Cardiogenic Shock (if yes, specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Post-cardiac surgery (not in cardiogenic shock)

Coronary revascularization (not acute MI)

Procedural support (specify, e.g., EP ablation, structural heart disease intervention, etc.):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Temporary MCS Explanation CRF Elements**

Explant Date/Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Reason for temporary MCS explant (select all that apply):*

Device malfunction

Device thrombosis

Infection

Recovery

Transplant (If transplant, specify if emergently transplanted):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Durable MCS transplant

Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Vascular closure method (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did subject have another MCS device implanted?

Yes (if yes, specify device type):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

**Adverse Events** (*Reference the MCS ARC consensus Definitions from Kormos et al. JHLT 2020; 39:735-750 document for categorization and formal definitions of each Adverse Event*)

Bleeding events (within 30 days of implant):

Yes (if yes, specify type)

No

Type 1

Type 2

Type 3

Type 3a

Type 3b

Type 4

Type 5

Type 5a

Type 5b

The association of the bleeding event should be classified as follow:

Patient-related

Management-related

Pump related

**MCS-Related Infection Adverse Events**

Yes (if yes, specify)

No

Percutaneous lead site infection

Superficial percutaneous lead infection

Deep percutaneous lead infection

Infection of external surfaces of an implantable component

Infection of blood-contacting surfaces of an implantable component (device endocarditis)

The association of the infection event should be classified as:

Patient-related

Management-related

Device-related

**Non-MCS-related Infections**

Yes (if yes, specify)

No

Infective Endocarditis: Non-MCS related

Blood Stream Infection (BSI)

Mediastinitis

Procedure-related mediastinitis

Non-MCS-related mediastinitis

Superficial mediastinal or thoracotomy wound infection

Sepsis

Localized non-MCS device infection

The association of the infection event should be classified as:

Patient-related

Management-related

Device-related

**Neurologic Dysfunction Adverse Events**

Yes (if yes, specify)

No

Type 1

Type 1a

Sub-type 1aH

Type 1b

Type 1c

Type 1d

Type 1e

Type 1f

Type 2

Type 2a

Sub-type 2aH

Type 2b

Type 3

Type 3a

Type 3b

*The association of the neurologic event should be classified as:*

Patient-related

Management-related

Device-related

*Severity, recovery, and long-term disability of neurologic dysfunction:*

Acute severity

Mild neurologic dysfunction

Moderate neurological dysfunction

Severe neurologic dysfunction

Stroke Recovery

Stroke with complete recovery

Stroke Disability

Fatal stroke

Disabling stroke

Non-disabling stroke

**Renal Dysfunction Adverse Events**

*Acute Renal Dysfunction:*

Yes (if yes, specify)

No

Stage 1

Stage 2

Stage 3

*Chronic Renal Dysfunction:*

Yes

No

The association of the renal dysfunction event should be classified as follows:

Patient-related

Management-related

Device-related

**Other Adverse Events**

*Cardiac Arrhythmias:*

Yes (if yes, specify)

No

Sustained ventricular arrhythmia

Sustained supraventricular arrhythmia

The association of the cardiac arrythmia event should be classified as:

Patient-related

Management-related

Device-related

*Respiratory Failure:*

Yes (if yes, specify)

No

The association of the respiratory failure event should be classified as follows:

Patient-related

Management-related

Device-related

*Venous Thromboembolism:*

Yes

No

*Hepatic Dysfunction:*

Yes

No

*Arterial non-CNS Thromboembolism:*

Yes

No

**Temporary MCS Device-Specific Adverse Events**

*Hemolysis:*

Yes (if yes, specify)

No

Minor hemolysis

Major Hemolysis

**Vascular Access Site Adverse Events**

Yes (if yes, specify)

No

Minor Complications (treated without the need for surgical intervention)

Major complications (required surgical or endovascular intervention)

Device Malfunction

Device failure

Device malfunction

The association of the vascular access site event should be classified as follows:

Patient-related

Management-related

Device-related

**Temporary MCS Hospitalization Characteristics*:***

Number of days in ICU post implant:\_\_\_\_\_\_\_\_\_\_\_

Was the subject discharged?

Yes (if yes, date of discharge):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Discharged to:

Home

Inpatient acute rehabilitation facility

Skilled nursing care facility/subacute rehabilitation facility

Hospice

Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No