**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