General Comments about Hemodynamic Module:

1. This module may be deployed at multiple time points throughout a trial: For example, immediately before and then at several time points after implantation of a temporary mechanical circulatory support (MCS) device.

2. The data elements (heart rate, systolic blood pressure, hemoglobin) from the baseline core lean CRF may change significantly when mechanical circulatory support is used and hemodynamic measurements are obtained. As these data elements are critical to hemodynamic calculations, they will need to be collected at the date and time closest to when the hemodynamic measurements are obtained.

3. Hemodynamic measurements should be obtained at rest (versus with exercise) and utilizing proper technique (transducers appropriately calibrated and zeroed, with end-expiratory mean values recorded).

4. Consider collection of waveforms and utilization of a hemodynamics core laboratory if the accuracy of the hemodynamic data is critical to the clinical trial.

Data elements that will not be collected, but can be calculated from the Baseline Lean CRF and Hemodynamic Module:

Body surface area:_____
Mean arterial blood pressure:_____
Mean pulmonary artery pressure:_____
Cardiac index:_____
Stroke volume:_____
Pulmonary vascular resistance:_____
Systemic vascular resistance:_____
Right ventricular stroke work index:_____
Pulmonary artery pulsatility index:_____
Cardiac power output:_____

Hemodynamic Module:

Data Elements to Collect:

Mechanical Ventilation

☐ Yes
☐ No
If yes, specify amount of positive pressure:_____

Non-invasive Positive Pressure Ventilation

☐ Yes
☐ No
If yes, specify amount of positive pressure:_____

Oxygen Supplementation

☐ Yes
☐ No
If yes, specify amount (FiO2 or L/min):_____

Temporary MCS Device

☐ Yes
☐ No
If yes, specify device and settings:_____

Intravenous Inotropes

☐ Yes (if yes, specify)
☐ No
- ☐ Dobutamine, If yes, specify dose:_____
- ☐ Milrinone, If yes, specify dose:_____
- ☐ Epinephrine, If yes, specify dose:_____
- ☐ Other (specify):_____, If other, specify dose:_____

Intravenous or Inhaled Vasoactive Medications

☐ Yes (if yes, specify)
☐ No
- ☐ Nitroprusside, If yes, specify dose:_____
- ☐ Nitroglycerin, If yes, specify dose:_____
- ☐ Norepinephrine, If yes, specify dose:_____
- ☐ Vasopressin, If yes, specify dose:_____
- ☐ Phenylephrine, If yes, specify dose:_____
- ☐ Epoprostenol, If yes, specify dose:_____
- ☐ Inhaled nitric oxide, If yes, specify dose:_____
- ☐ Other (specify):_____, If other, specify dose:_____

Hemodynamics Data Elements to Collect

PA Catheter Implant: Date/Time (in 24-hour format, e.g. 16:04):_____

Sinus Rhythm
☐ Yes
☐ No
If no, specify rhythm :
- ☐ AFib
- ☐ Aflutter
- ☐ Atach
- ☐ AV paved
- ☐ Other (specify):_____

Heart Rate: BPM (mmHg):_____
Systolic Blood Pressure (mmHg):_____
Diastolic Blood Pressure (mmHg):_____
Right Atrial Pressure (end expiratory measurement) (mmHg):_____
Pulmonary Artery Systolic Pressure (mmHg):_____
Pulmonary Artery Diastolic Pressure (mmHg):_____
Pulmonary Capillary Wedge Pressure (end expiratory measurement) (mmHg):_____
Pulmonary Capillary Wedge Pressure – V Wave in Wedge Positions (end expiratory measurement) (mmHg):_____

LVEDP (if performed)
Cardiac Output (L/min):_____
- Specify method: Thermodilution ☐ or Fick ☐
- Specify method to measure oxygen uptake if using Fick: _____
- Specify amount of tricuspid regurgitation if using Thermodilution:_____

Hemoglobin (g/dL):_____
Arterial Oxygen Saturation (%):_____
Pulmonary Artery Saturation (%):_____