Chapter 100.  Right Heart Catheterization (RHC)

This manual is intended to serve as both a training and a reference document for persons who perform the right heart catheterization for the PVDOMICS study using standardized procedures and techniques. This will aid in obtaining accurate test results and a safe testing environment.

100.1 Right Heart Catheterization Overview

Right heart catheterization is a clinical test used to determine the pressures in the chambers of the heart and the lungs. A pulmonary artery catheter is introduced into the right side of the heart and then passes into the pulmonary artery.

In addition to the pressures in the heart and lungs, other tests may be done during the right heart cath to further determine the health of the patient. For example, vasodilators may be given to determine the patient’s response.

The most common indications for the right heart cath include assisting in the diagnosis and/or management of:

1. Heart failure
2. Pulmonary Hypertension
3. Shock
4. Cardiomyopathy
5. Congenital heart disease
6. Valvular heat disease
7. Pre or post heart transplant assessment

100.2 Quality Control

Quality Control (QC) is the periodic testing of a system to verify that it meets specifications. For example, all machines used for the right heart cath procedures should be regularly calibrated per manufacturer’s instructions to ensure proper function.

All personnel performing QC checks should be familiar with all procedures to ensure that no technique errors are made. All QC testing data should be saved per the study site’s normal protocol.

100.3 Personnel Qualifications

a. All persons performing the right heart catheterizations will be licensed medical practitioners in the state where the procedure is taking place.
b. Residents or fellows will be supervised by an attending physician who will be present during the entirety of the procedure.

c. All persons performing the right heart catheterizations will be trained in the specific study procedures by the data coordinating center (DCC) via webinar instruction.

100.4 Site Certification for the PVDOMICS Study

Before right heart catheterizations may be performed on study participants, each site will be required to complete the following list of requirements:

1. Review and become familiar with this MOP and study all procedures
2. Establish a primary contact person at their site who will be responsible for communication with and transmission of data to the DCC.
   a. This individual should ensure that they have completed Form 10 (Study Personnel Form) prior to transmitting any data.
3. Obtain training on the study protocol.
4. Send two example files following the protocol described in Manual of Operations Chapter 101 (Right Heart Catheterization Transmission). These files will be reviewed by the DCC Cardiovascular Physiology Core (CPC) for quality and readability.
5. Receive approval from the DCC to proceed with testing of participants.

100.5 DCC Over-read Procedure

Each right heart catheterization report sent to the DCC will be reviewed by a cardiology fellow and a cardiology staff member to verify data quality and reliability.

100.6 Equipment and Supplies

1. Pulmonary Artery (Swan-Ganz) catheter
   a. Size is at least 6F
2. Monitor, transducer, and pressure tubing
3. ECG cart & supplies
   a. Must be able to capture ECG waveform during each pressure measurement
4. Pulse oximeter
5. Blood pressure cuffs (assorted sizes)
6. Skin prep (e.g. 2% chlorhexidine)
7. Local anesthesia (e.g. 2% lidocaine solution)
8. Sterile supplies (for staff and participant)
   a. gown, gloves, hat, and mask
   b. drape for participant
   c. flush for catheter
   d. ultrasound probe cover and gel
9. Introducer sheath and needle
   a. Sheath size used should be at least one French size larger than the size of the PA catheter to enable simultaneous RA measurements at the side port of the sheath.
10. Resuscitation cart
    a. Airway management equipment
    b. Defibrillator
    c. Airway suction apparatus, tubing, and disposable ends
    d. Emergency medications (e.g. epinephrine, lidocaine, and nitroglycerine)
11. Supplemental O2 equipment and delivery systems

100.7 Participant Contraindications and Safety
The contraindications for performing the right heart cath include those below. However, this list should not replace good clinical judgment. Any questions regarding exercise eligibility should be brought to the attention of the site principal investigator.

1. Absolute Contraindications
   a. Infection at the insertion site
   b. Presence of a right ventricular assist device or total artificial heart
   c. Inability to provide consent

2. Relative Contraindications
   a. Coagulopathy (INR > 3.0)
   b. Thrombocytopenia (< 50,000)
   c. Electrolyte imbalances/disturbances
   d. Acid-base disturbance
   e. Other conditions that may make passage of the swan difficult (e.g. tricuspid valve prosthesis or vegetation)
100.8 Pre-Test Instructions for the Participant

1. Participant instructions:
   a. Loose-fitting, wrinkle resistant and comfortable clothing is recommended for the participant’s comfort.
   b. The participant should abstain from eating for at least 6 hours prior to the test or as required by the study site’s normal catheterization protocol.
   c. Anticoagulant medications (warfarin, NOACs, Lovenox, heparin, DTIs) should be managed prior to the right heart cath by the performing physician. This management will include determining acceptable INR values for each participant and deciding whether or not anticoagulant medications will be withheld prior to the procedure. However:
      i. Participants must be off of heparin for at least 30 minutes prior to procedure.
      ii. Participants must be off of low molecular weight heparin for at least 8 hours prior to the procedure.
   Other medications (diuretics, diabetic medications) should also be held or continued at the discretion of the site PI or performing physician.
   d. For participants who receive sedation during the procedure, a responsible adult must be available to drive the participant home following the procedure unless otherwise stipulated by the study site.

2. Obtain consent for the right heart catheterization procedure.
   a. Explain the procedure and answer the participant’s questions before the test.
   b. If the participant will be sedated, the consent process must be done prior to any sedation.

100.9 Participant Assessment and History

1. The participant’s medical history, clinical diagnosis, and reason for the test should be reviewed by the performing physician or designated trained professional. The review should include the following:
   a. Current medications (e.g., aspirin, medications for control of blood pressure, beta-blockers, etc.) and time of last dose.
      i. This may already have been noted for a prior study procedure. Verify that the information is still correct.
   b. Fasting status. Participants should be fasting for the omics blood draws associated with the right heart catheterization.
c. Pulmonary function tests, blood gas data, blood chemistry results, echocardiogram, baseline ECG, etc.

d. Current symptoms including chest pain, discomfort, edema, or wheezing.

e. Any other results required by the study site’s normal catheterization protocol.

2. If there is a language barrier an interpreter will be used as per the study site’s normal protocol.

3. Ask each participant if they complied with the preparation procedures.
   a. Record the time of the participant’s last meal.
   b. Record if heparin/low-molecular weight heparin was withheld as instructed.

100.10 PVDOMICS RHC Procedure Overview

1. The participant should be in the same position for each set of hemodynamic measurements at each study time point. Participants will be in a supine position for resting right heart catheterization measurements.

2. Exclude participants on any positive pressure ventilation (CPAP, BiPAP or ventilator) during the procedure.

3. Per protocol of the study site, participants will have continuous monitoring of their heart rate, EKG, blood pressure (noninvasive cuff and/or arterial line at some sites), and pulse oximetry.

4. Venous access will be obtained via the internal jugular vein, femoral vein, or antecubital vein.
   a. The right internal jugular vein is the preferred access as this will easily allow venous blood to be sampled from the superior vena cava via the large-bore side-port of the introducer, which will decrease the risk of “shearing” of the blood sample.
   b. Femoral vein access is the least preferred option.
   c. The pulmonary artery catheter size should be at least 6F to prevent shearing of blood samples.
   d. The participant will be prepped and draped in a sterile fashion.
   e. Use of moderate conscious sedation will be at the discretion of the study site and per their protocol.
   f. The area of venous access will be anesthetized with local anesthetic.
   g. The introducer will be placed using the modified Seldinger's technique.
   h. The pulmonary artery catheter will be placed through the introducer, the catheter will be oriented so that its curve facilitates passage through the cardiac chambers, and the catheter will be advanced through the introducer while the pressure at its tip is transduced.
i. Fluoroscopy will be used for insertion of catheter.

5. The operator must have an unobstructed view of the hemodynamic monitor during the entire procedure.

6. The balloon should be fully inflated whenever the catheter is advanced and completely deflated whenever the catheter is withdrawn.

7. Once the catheter tip has reached the pulmonary artery (PA), it will be advanced until the pulmonary capillary wedge pressure (PCWP) is identified by a decrease in the pressure combined with a change in the waveform.

8. The following pressures will be measured during the study procedures:
   a. Right atrium (RA) pressure
   b. Right ventricle (RV) pressure (systolic and end-diastolic)
      i. Measured during the resting RHC only
   c. Pulmonary capillary wedge pressure (PCWP)
   d. Pulmonary artery (PA) pressure (systolic and diastolic)

9. The following saturations will be measured during the resting RHC only, while the participant is breathing spontaneously:
   a. SVC oxygen saturation (SVC sat)
   b. RA oxygen saturation (RA sat)
   c. PA oxygen saturations (PA sat)
   d. PCWP oxygen saturations (PCWP sat)

10. Thermodilution cardiac output (TDCO) will measured in triplicate during all study procedures.
    a. If there is >10% variability between measurements additional measurements should be taken until three (3) are in agreement. The three in agreement will then be averaged.

11. The following blood samples will be obtained during the resting RHC per the blood protocol. All blood samples must reach the lab within 1 hour of the draw time.
    a. Venous sample from the superior vena cava (before RHC) (27.5mL) The venous "OMICS" blood sample should be drawn from the side-port of the introducer if the internal jugular is accessed and the PA catheter advanced into the SVC in the event of femoral or antecubital access.
    b. Systemic Arterial (optional, before RHC) (6.5mL)
    c. Pulmonary Capillary (Wedge) (6.5mL)
100.11 Order of Procedures

1. All participants, excluding normal controls, will undergo right heart catheterization in the supine position at rest.¹
   a. All pressures and cardiac outputs as described in section 100.13 “Individual measurements” below will be measured.

2. Participants will then receive an oxygen challenge with 100% oxygen by face mask for 5 minutes. CO₂ retainers (i.e. pH < 7.32 and pCO₂ > 50) and those with mPAP < 20 mmHg will be excluded from the oxygen challenge unless, in the judgment of the site PI, the test can be performed safely.
   a. Remeasure all pressures, saturations and cardiac outputs as described in section 100.13 “Individual measurements” below.

3. Participants with PCWP < 25 mmHg will then undergo a vasodilator challenge. Participants will be excluded from the vasodilator challenge if their PCWP ≥ 25 mmHg or if their mPAP < 20 mmHg.
   a. Continue 100% oxygen through face mask. Oxygen should not be stopped between the oxygen challenge and the vasodilator challenge.
   b. Add inhaled nitric oxide (NO) at 40 ppm through face mask along with 100% oxygen for 5 minutes.
   c. Remeasure all pressures, saturations and cardiac outputs as described in section 100.13 “Individual measurements” below.

4. Participants will then undergo either an invasive CPET (iCPET) or a fluid challenge.
   a. Participants will be excluded from the fluid challenge if they have a baseline RAP ≥ 15 or a PCWP ≥ 18 mmHg.
   b. For participants undergoing invasive CPET:
      i. iCPET will be performed using the metabolic cart at each site per their protocol.
      ii. Participants with femoral access cannot undergo invasive CPET.
      iii. Remeasure all pressures and cardiac outputs as described below after settling on ergometer.
      iv. Variables and data for CPET must also be measured and recorded. (Reference: Manual of Operations Chapter 111)

¹ Note: RHC should be completed before angiography if a left heart catheterization is to be done at the same time.
c. For participants undergoing the fluid challenge:
   i. Give 500 ml of 0.9% room temperature saline over 10 minutes through the side arm of the introducer. Infusion can begin immediately following iNO challenge with no waiting period.
   ii. Remeasure all pressures, saturations and cardiac outputs as described in section 100.13 “Individual measurements” below.

100.12 Operator Measurements and Recording Data

1. All pressure tracings must be accompanied by a simultaneous ECG tracing (directly above or below the pressure tracing) which is used for timing and analysis of waveforms.

2. All pressure tracing recordings or “snapshots” should contain at least three (3) entire respiratory cycles.
   a. If the recordings contain premature ventricular contractions (PVCs), the tracings should be re-recorded unless PVC burden is too high to allow for a PVC-free recording.
b. Measurements will be recorded by sites and paper waveforms will be sent to the study coordinator for each pressure measurement.

3. Hemodynamic measurements during the resting RHC should be taken twice, once at end-expiration while the participant is breathing spontaneously and once during an end-expiratory breath hold. The resting RHC is the only time an end-expiratory breath hold will be used.
   a. Patients will be coached on the proper way to perform a breath hold. They will be asked to inspire and then relax as they expire. Care must be taken to avoid Valsalva. A suggested coaching script is attached (Appendix 3).

4. Hemodynamic measurements during the oxygen challenge, vasodilatory challenge, fluid challenge and/or iCPET will only be measured while the participant is breathing spontaneously.

5. Digitized or computer generated “mean line” should be on and recorded with all tracings.
   a. The mean line should always be recorded.
   b. If there is disagreement between the mean line and the interpretation by the reader, the human reader’s interpretation will take precedence.
      i. If this is the case, saved images and paper waveforms sent to the study coordinator or the DCC should be representative of the human reader’s interpretation.

6. Prior to recording any measurements:
   a. Ensure that all recording equipment has been calibrated as per manufacturer’s instructions.
   b. Check the pressure transducer level to ensure it is at the level of the right atrium.
   c. “Zero” the transducer. To do this:
      i. The stopcock closest to the transducer is closed to the patient.
      ii. Remove the sterile protective cap from the stopcock port, exposing the hemodynamic monitoring system to air.
      iii. The monitor's zero function key is activated to offset pressure in the transducer, setting the pressure to zero.
      iv. Open the stopcock to the patient and replace the sterile cap on the stopcock port.
      v. Zeroing ensures that when the transducer stopcock is open to the patient and closed to air, the only pressure on the transducer will be from the vessel/heart chamber being monitored.
      vi. The transducer should be “zeroed” before each condition.
1. For participants undergoing an invasive CPET, the following procedure will be used for calibration. The PA and PCWP are recorded under fluoroscopy to ensure proper location of the catheter tip. The patient is then moved to the upright position, and the pressure calibrator is opened to ambient air (“zeroed”), calibrated, and leveled to the fourth intercostal space at the midaxillary line, approximately 5 cm below the angle of Louis or 3 finger breadths below the axilla. (see Manual of Operations Chapter 111 (iCPET))

7. Do not record any data while the patient is restless, talking, or coughing.

8. If pressure tracings appear dampened (for example, no dicrotic notch is seen on the PA pressure tracing), re-flush the catheter and ensure that there are no air bubbles in the pressure tubing.

9. If excessive catheter whip or “ringing” is noticed, attempt to reposition catheter to a less turbulent area. Introducing a small amount of blood into the line may be helpful although care must be taken to not overdamp the signal.

100.13 Individual measurements

1. Venous “OMICS” Blood Draw

   a. Make sure the participant has been resting by laying down on the cath lab table for 10 minutes before drawing the blood. During this resting period, patients can be prepped and draped, and the sheath can be placed.

   b. Draw the venous blood sample from the SVC. The preferred site of access for right heart catheterization is the right internal jugular vein. In this position, the venous "OMICS" blood sample should be drawn from the side-port of the introducer, which lies in the superior vena cava. Using the large-bore side-port of the introducer decreases the risk of "shearing" of the blood sample, which is why this site is preferred. There are differences between femoral, inferior vena cava and superior vena cava blood from an "OMIC" perspective. Therefore, if a femoral or antecubital approach is being used, the PA catheter will need to be advanced into the SVC for the "OMICS" venous blood draw before advancing into the pulmonary artery.

   c. Draw back 3mL of blood using a sterile syringe and discard the sample. Then, using a second sterile syringe, draw 27.5mL of blood for “omics” analysis.

   d. Transfer the blood from the sterile syringe to the appropriate blood collection tubes using a blood transfer device.

      i. We suggest having a study coordinator or other team member designated to transfer the blood from the syringe to the appropriate vacutainers and then transport the blood samples to the lab.
ii. Fill the blood collection tubes in the following order, taking care to note which tubes go on ice and which are kept at room temperature.

Order of Right Heart Catheterization Venous Blood:

<table>
<thead>
<tr>
<th>Order</th>
<th>Blood Type</th>
<th>Color</th>
<th>Additive</th>
<th>Volume</th>
<th>Core</th>
<th>Transport to Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Resting Venous</td>
<td>Red</td>
<td>RNA Preservative</td>
<td>2.5 mL</td>
<td>Genomic</td>
<td>Room Temperature</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Resting Venous</td>
<td>Lavender</td>
<td>EDTA</td>
<td>10 mL</td>
<td>OMICS</td>
<td>Wet Ice</td>
</tr>
<tr>
<td>3</td>
<td>Resting Venous</td>
<td>Lavender</td>
<td>EDTA</td>
<td>10 mL</td>
<td>OMICS</td>
<td>Wet Ice</td>
</tr>
<tr>
<td>4</td>
<td>Resting Venous</td>
<td>Gold</td>
<td>SST</td>
<td>5 mL</td>
<td>Bank</td>
<td>Wet Ice</td>
</tr>
</tbody>
</table>

2. **Optional** Arterial Blood Draw for Arterial Blood Gas (ABG) Analysis
   a. At the same time as the venous blood draw, after 10 minutes of rest and before any other procedures or measurements are performed, arterial blood may be drawn for an ABG. This is **not** required.
   b. If arterial blood for ABG analysis was already obtained during PFT testing it should **not** be repeated during the RHC.
   c. Draw 1mL of blood for ABG in a **heparinized** syringe and then 6.5mL of blood for “omics” analysis in a **non-heparinized** syringe.
      i. ABG analysis should be done at the local site and the values recorded on the appropriate PVDOMICS form.
      ii. The rest of the blood should be transferred to the appropriate blood collection tubes using a blood transfer device and delivered to the lab with the venous blood for processing and shipping to the Biorepository Core.

1. Fill the blood collection tubes in the following order, taking care to note which tubes go on ice and which are kept at room temperature.

Order of Systemic Arterial Blood Collection:

<table>
<thead>
<tr>
<th>Order</th>
<th>Blood Type</th>
<th>Color</th>
<th>Additive</th>
<th>Volume</th>
<th>Core</th>
<th>Transport to Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Resting Systemic Arterial</td>
<td>Lavender</td>
<td>EDTA</td>
<td>4 mL</td>
<td>OMICS</td>
<td>Wet Ice</td>
</tr>
<tr>
<td>2</td>
<td>Resting Systemic Arterial</td>
<td>Red</td>
<td>RNA Preservative Solution</td>
<td>2.5 mL</td>
<td>Genomic</td>
<td>Room Temperature</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PAX gene®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Superior Vena Cava Oxygen Saturation (SVC sat)
a. During the baseline hemodynamic measures, all participants should have at least one SVC and at least one mid-RA oxygen saturation measured to exclude significant intracardiac shunting.
   i. SVC sat can be obtained from either the IJ sheath or from the right atrium.
   ii. Draw 1mL of blood for a SVC sat.
      1. If your site requires more than 1mL for a SVC sat, draw the minimum amount of blood allowed by your site’s lab for this analysis.

4. Right Atrial Pressure Tracing (RAP)
   a. Record mean pressure (defined as the mean of the a wave).
      i. If the participant is in atrial fibrillation, use mid c wave or the Z point (point which corresponds to the end of the QRS).
   b. Record peak a wave and peak v wave.
   c. Apart from baseline measurements during the resting RHC, all subsequent RAP measurements (i.e. those measured during the challenges) will be simultaneously performed via transduced pressures from side port of venous sheath. Therefore, direct calibration between side port RAP/CVP pressure and PA catheter derived RAP should be made at baseline before advancing the catheter.

5. Right Ventricular Pressure (RVP) Tracing
   a. Record peak RV systolic pressure at end-expiration.
   b. Record RVEDP (pressure just prior to rise of the RV pressure).
   c. RV pressures are only recorded during the resting RHC (baseline measurements).

6. Pulmonary Capillary Wedge Pressure (PCWP) Tracing
   a. After RV pressure tracing, catheter is advanced with balloon inflated into the pulmonary artery and immediately out to the PCWP position.
   b. After PCWP recording, a pulmonary capillary wedge oxygen saturation (PCWP sat) should be measured.
      i. While the balloon is inflated, and from the distal port of the PA catheter, slowly draw back at least 3mL of blood until the blood sample turns bright red. Discard this sample.
      ii. Draw 1mL of blood for a PCWP sat.
         1. If your site requires more than 1mL for a PCWP sat, draw the minimum amount of blood allowed by your site’s lab for this analysis.
iii. PCWP sat should be at least 90% (assuming the arterial saturation measured by pulse oximetry is at least 90%). If PCWP saturation is < 90%, reposition the catheter, re-record PCWP tracing, and re-draw PCWP saturation.

1. After two attempts, if PCWP sat is still < 90% but operator deems fluoroscopy and waveforms are sufficient to confirm wedge, you may proceed without obtaining PCWP sat ≥ 90%.

2. If PCWP saturation cannot be obtained after 3 attempts, please note “PCWP sat is unable to be obtained” and continue.

iv. Deflate balloon and flush catheter.

c. Record mean pressure (defined as the mean of the a wave).
   i. If the participant is in atrial fibrillation, use mid c wave or the Z point (point that corresponds to the end of the QRS).

d. Record peak a wave and peak v wave.

7. Pulmonary Capillary Wedge “omics” Blood Draw

   a. Blood draw must be done after all pressure measurements have been completed.

   b. If PCWP saturation remained < 90% after 3 attempts (as described above), do not draw the PCW “omics” blood.

   c. Draw back 3mL of blood using a sterile syringe and discard the sample. Then, using a second sterile syringe, draw 6.5mL of blood for “omics” analysis as per blood protocol.

      i. If at any time during the blood draw the participant becomes intolerant (e.g. coughing), the blood draw can be stopped. In this case the full blood sample will not be collected.

   d. Transfer the blood from the sterile syringe to the appropriate blood collection tubes using a blood transfer device. Fill the blood collection tubes in the order noted in the following table, taking care to note which tubes go on ice and which are kept at room temperature.

Order of Pulmonary Capillary (Wedge) Blood Collection:

<table>
<thead>
<tr>
<th>Order</th>
<th>Blood Type</th>
<th>Color</th>
<th>Additive</th>
<th>Volume</th>
<th>Core</th>
<th>Transport to Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pulmonary Capillary “Rest Wedge”</td>
<td>Lavender</td>
<td>EDTA</td>
<td>4 mL</td>
<td>OMICS</td>
<td>Wet Ice</td>
</tr>
<tr>
<td>2</td>
<td>Pulmonary Capillary “Rest Wedge”</td>
<td>Red PAX gene®</td>
<td>RNA Preservative Solution</td>
<td>2.5 mL</td>
<td>Genomic</td>
<td>Room Temperature</td>
</tr>
</tbody>
</table>
8. Diastolic Pressure Gradient (DPG)
   a. Measure pulling back from PCWP to PA tracing at end-expiration.

9. Pulmonary Artery Pressure (PAP) Tracing and Saturation
   a. After PCWP measurement, deflate balloon and pull back catheter approximately 1 cm. Record PAP tracing.
   b. Record PA systolic pressure and PA diastolic pressure, measured at end-expiration
   c. Record mean PA pressure (use the AUC provided by the computer).
      i. The mean PA pressure will be verified by the core lab using the equation: 
         \[ mPAP = \frac{1}{3}(PASP) + \frac{2}{3}(PADP) \]
   d. After PAP tracing is recorded, pull back and discard 3mL of blood from the distal port. Then draw 1mL of blood, analyze, and record saturation.
      i. If your site requires more than 1mL for the PA sat, draw the minimum amount of blood allowed by your site’s lab for this analysis.

10. Pulmonary Artery (PA) “omics” Blood Draw
   a. Blood draw must be done after all pressure measurements have been completed.
   b. Draw back 3mL of blood using a sterile syringe and discard the sample. Then, using a second sterile syringe, draw 6.5mL of blood for “omics” analysis as per blood protocol.
      i. Note that if the catheter is not flushed between drawing the blood for the PA sat and drawing the “omics” blood it is not necessary to draw back the 3mL of waste prior to the “omics” draw. If the catheter is flushed after drawing the PA sat then 3mL of blood must be drawn and discarded before the “omics” blood is collected.
   c. Transfer the blood from the sterile syringe to the appropriate blood collection tubes using a blood transfer device. Fill the blood collection tubes in the order noted in the following table, taking care to note which tubes go on ice and which are kept at room temperature.

Order of Pulmonary Arterial (Mix) Blood Collection:

<table>
<thead>
<tr>
<th>Order</th>
<th>Blood Type</th>
<th>Color</th>
<th>Additive</th>
<th>Volume</th>
<th>Core</th>
<th>Transport to Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pulmonary Artery “Rest Mix”</td>
<td>Lavender</td>
<td>EDTA</td>
<td>4 mL</td>
<td>OMICS</td>
<td>Wet Ice</td>
</tr>
<tr>
<td>2</td>
<td>Pulmonary Artery “Rest Mix”</td>
<td>Red PAX gene®</td>
<td>RNA Preservative Solution</td>
<td>2.5 mL</td>
<td>Genomic</td>
<td>Room Temperature</td>
</tr>
</tbody>
</table>
11. Cardiac Output
   a. All sites will obtain thermodilution cardiac output (TDCO). A direct Fick cardiac output will also be obtained if the site is able to do so. Fick cardiac output cannot be obtained while the participant is receiving supplemental oxygen.
   b. Thermodilution Cardiac Output (TDCO)
      i. Prior to each participant enrollment, software should be checked to ensure proper information is input into computer system for proper calibration of cardiac output including type and size of pulmonary artery catheter, size of saline bolus (i.e. 10cc), temperature of saline, computational constant, etc.
      ii. TDCO should be made in triplicate and the final result will be the average of three measurements.
      iii. If individual measures vary more than 10% from each other, additional measurements should be taken until three (3) are in agreement. The three in agreement will be used to determine the average.
      iv. TDCO measurements can be skipped in the presence of known systemic to pulmonary shunt with Qp/Qs >1.5 as TDCO may not be reliable if there is a large shunt.
   c. Direct Fick Cardiac output
      i. VO₂ will be obtained using the metabolic cart. Arterial saturation will be either directly measured from an arterial line if available or pulse oximetry will be used as the arterial saturation.
      ii. See below in “Calculations” section for direct Fick calculation.

100.14 Recording Results:
1. Results will be recorded on the paper copy of Form 280 (Right Heart Catheterization) and will then be entered into the electronic database by the study coordinator.
2. File the paper copy of the participant’s results in their study file maintained on site.

100.15 Procedure Notes:
1. Record thorough notes of the procedure including:
   a. Medications taken prior to procedure
b. All procedure notes required for clinical documentation

2. Note any results that could not be obtained.
   a. Include the reason the results could not be obtained. Be specific.
   b. File a protocol deviation.

3. Make note of any other protocol deviations or unexpected findings.

100.16 Calculations

In general, calculations will be performed by a computerized data acquisition system or database software and will not need to be calculated by the technician. However, if the values below are not automatically calculated by either the system software or the database, manual calculations will be performed according to the equations below from measurements obtained during the RHC.

1. Body Surface Area (BSA)

\[
BSA = \frac{\sqrt{\text{height (cm)} \times \text{weight (kg)}}}{60}
\]

2. Direct Fick Cardiac Output

\[
\text{Fick (L/min)} = \frac{\text{measured VO2 (ml/min)}}{(\text{Art O2 sat} - \text{MVO2}) \times 1.34 \times \text{Hb} \times 10}
\]

3. Stroke Volume (SV)
   a. Use direct Fick cardiac output if available, otherwise use thermodilution cardiac output. Note which is used.

\[
\text{SV} = \frac{\text{Cardiac Output (CO)}}{\text{Heart Rate (HR)}}
\]

4. Stroke Volume / Pulmonary Artery Pulse Pressure (SV/PP)
5. Pulmonary Vascular Resistance (PVR)
   a. Use direct Fick cardiac output if available, otherwise use thermodilution cardiac output. Note which is used.
   \[
   \text{PVR} = \frac{\text{mean } \text{PAP} - \text{mean } \text{PCWP}}{\text{CO}}
   \]

6. Systemic Vascular Resistance (SVR)
   a. Use direct Fick cardiac output if available, otherwise use thermodilution cardiac output. Note which is used.
   \[
   \text{SVR} = \frac{\text{MAP} - \text{mean } \text{RAP}}{\text{CO}}
   \]

7. Right Ventricular Stroke Work Index (RVSWI)
   \[
   \text{RVSWI} = \frac{\text{mean } \text{PAP} - \text{mean } \text{RAP}}{\text{SV/BSA}}
   \]

8. Shunt Fraction (Qp/Qs)
   a. Art \(O_2\) sat may be obtained from an arterial line, or the pulse oximetry \(O_2\) saturation may be used instead.
   \[
   \frac{\text{Qp}}{\text{Qs}} = \frac{\text{Art } O_2 \text{ sat} - \text{SVC sat}}{\text{Art } O_2 \text{ sat} - \text{PA sat}}
   \]

9. Mean PA Pressure (mPAP)
   a. This formula will be utilized by the PVDOMICS database to calculate mean PA.
   \[
   \text{mPAP} = \frac{\text{PASP} + 2\text{PADP}}{3}
   \]
### 100.17 Terms and Definitions

1. **ABG** Arterial Blood Gases  
2. **Art O₂ sat** Arterial oxygen saturation  
3. **BSA** Body Surface Area  
4. **DBP** Diastolic Blood Pressure  
5. **DPG** Diastolic pressure gradient  
6. **Fick CI** Direct Fick Cardiac Index  
7. **Fick CO** Direct Fick Cardiac Output  
8. **FIO₂** Fraction of inspired Oxygen  
9. **Hb** Hemoglobin  
10. **HR** Heart Rate  
11. **MAP** Mean Blood Pressure  
12. **mPAP** Mean pulmonary artery pressure  
13. **Mean PCWP** Mean Pulmonary capillary wedge pressure  
14. **Mean RAP** Mean Right Atrial Pressure  
15. **O₂ sat** Oxygen Saturation  
16. **PA O₂** Pulmonary artery saturation  
17. **PADP** Pulmonary artery diastolic pressure  
18. **PASP** Pulmonary artery systolic pressure  
19. **PCWP a** Pulmonary capillary wedge pressure, a wave  
20. **PCWP sat** Pulmonary capillary wedge saturation  
21. **PCWP v** Pulmonary capillary wedge pressure, v wave  
22. **PVR** Pulmonary vascular resistance  
23. **Qp/Qs** Shunt fraction  
24. **RA a** Right Atrial a wave  
25. **RA v** Right Atrial v wave  
26. **RVEDP** Right ventricular end-diastolic pressure
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**100.18 References:**


Appendices appear on the following pages.
100.A.1 Appendix 1 – RHC Blood Draw Flow Sheet

1. Participant must rest for 10 min before blood collection

Side port of introducer

Arterial access

2. VENOUS blood collection
   Discard 3ml
   OMICS blood: 27.5ml
   1. 2.5ml Red PAX gene (RT)
   2. 10ml Lavender (ice)
   3. 10ml Lavender (ice)
   4. 5ml Gold (ice)

Optional
2a. SYSTEMIC Arterial blood collection
   Discard 3ml
   Blood gas: 1ml
   OMICS blood: 6.5ml
   1. 4ml Lavender (ice)
   2. 2.5ml Red PAX gene (RT)

3. Resting RHC hemodynamic measurements

4. Measure PCW pressure

Distal port

5. Pulmonary Capillary (Wedge) blood collection
   Discard 3ml
   OMICS blood: 6.5ml
   1. 4ml Lavender (ice)
   2. 2.5ml Red PAX gene (RT)

6. Measure PA pressure

Distal port

7. Pulmonary Arterial (Mix) blood collection
   Discard 3ml
   OMICS blood: 6.5ml
   1. 4ml Lavender (ice)
   2. 2.5ml Red PAX gene (RT)

8. Thermodilution Cardiac Output

9. Oxygen Challenge in Supine Position

10. Vasodilatory Challenge in Supine Position


□ Order of RHC
□ Order of OMICS Blood Collection 2

* non-heparinized syringe
$ heparinized syringe
RT = room temperature
ice = place on wet ice

If OMICS Blood is collected during PEAK and POST exercise the following blood order (MOP Table 33.3) is recommended and is to be collected the same as during the resting right heart catheterization.
100.A.2 Appendix 2 – Example Pressure Waves

from Braunwald’s Heart Disease: A Textbook of Cardiovascular Medicine. Davidson, CJ, Bonow, RO, Published Jan 1, 2015, Pages 364-91, Figure 19-10.
During the resting RHC, hemodynamic measurements must be measured during an end-expiratory breath hold. Here is a suggested script for coaching participants on the proper way to perform an end-expiratory breath hold:

Explain to the participant: “In order to obtain accurate measurements, we will ask that you pause your breathing for short periods of time during the procedure. We would like for you to take a breath in, let it out, and then pause your breathing while we do the measurement. Please do this without bearing down or tightening up the stomach muscles.”

Have the participant practice the procedure: “Please try this now: Take a breath in, let it out, and pause your breathing.”

Take the measurement: “Again: Take a breath in, let it out, and pause your breathing.” (Take measurement) “Breath normally now.”

Do not use an end-expiratory hold for measurements taken during the challenges (oxygen challenge, vasodilatory challenge, fluid challenge, or invasive CPET).