

Chapter 101. Right Heart Catheterization (RHC) Data Transmission

This chapter is intended to serve as both a training and a reference document for persons who transmit the right heart catheterization data to the Cardiovascular Physiology Core (CPC) at the Data Coordinating Center (DCC). This will aid in obtaining accurate, good-quality test results.

101.1 Recording Results:

1. Results are recorded on a paper copy of Form 280-Clinical Center Right Heart Cath Results and then manually entered into the PVDOMICS database by the study coordinator. The paper version of Form 280 will be considered the source document.
 - a. If centers create their own worksheet for recording study data, this worksheet may be used as the source document instead, meaning that clinical centers will not be required to fill out a paper copy of Form 280.
 - i. Note: If centers use their own worksheet for recording data, it is recommended that results not be recopied onto Form 280 for 'neatness'. Data transcription/transposition can occur during copying.
 - b. All results must be entered into the PVDOMICS database regardless of paper document used.
2. File the paper copy of the participant's results (source document) in the study file maintained locally.

101.2 Procedure Notes:

1. Record thorough notes of the procedure including:
 - a. Medications taken prior to procedure
 - b. Condition of participant (e.g. had illness/cold a few days ago)
 - c. 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 with your center's IRB as appropriate per your center's IRB policies.
 - c. Make note of any other protocol deviations or unexpected findings at the bottom of the paper copy of Form 280 (Clinical Center Right Heart Catheterization Results Form).

101.3 RHC Data Transmission to Data Coordinating Center's Cardiac Physiology Core

1. What to Transmit
 - a. Documentation of hemodynamic measurements for each condition (resting, oxygen challenge, vasodilatory challenge, and oxygen challenge or iCPET) at each position (RA, RV (resting only), PCWP and PA).
 - b. One copy of the most representative wave form for each pressure measurement under each

condition (resting, oxygen challenge, vasodilatory challenge, and fluid challenge or iCPET)

- i. Images must capture 3 consecutive breath cycles (may be split across pages)
- ii. Images must include ECG tracing at the top (minimum of 3 leads)

2. De-Identify All Records

- a. All identifying information, other than the PVDOMICS specific study identifications, must be removed/redacted before transmitting the documents to the Cardiovascular Physiology Core at the DCC.
- b. Make sure **each page** has the correct PVDOMICS study identification information (PVDOMICS ID, alphacode, and date of testing) on it.
- c. Affixing labels with the PVDOMICS identifying information is acceptable.

- i. Example label:

RHC_987654_AC_12102016

3. Naming and Saving Files

- a. If possible, save study results directly as a **PDF** file.
- b. If results cannot be directly saved as a PDF document:
 - i. Print out results
 - ii. Scan results onto a desktop computer
 - iii. Save in PDF format
- c. Name the file according to the following convention:
 - i. RHC_*[PVDOMICS 6 digit ID number]*_*[two letter alphacode]*_*[date in mmddyyyy format]*.pdf
 - ii. For example: RHC_987654_AC_12102016.pdf
 - iii. Do not use any special characters in the file name.

4. Transmit Data to Cardiovascular Physiology Core (CPC) at the DCC

- a. Files will be transferred electronically to the Cardiovascular Physiology. This will allow the transfer of files in a secure and traceable fashion.
- b. Upload Right Heart Catheterization PDF file and send to CPC via secure data transfer protocol (see MOP Chapter 6, Appendix 1)

Following transfer, data files will be stored on a secure server that is protected within the firewall of Cleveland Clinic. The Cardiovascular Physiology Core will review each file received to verify that all data is complete and accurate. DCC programmers have internal protocols that are used to move and securely store PVDOMICS study data.