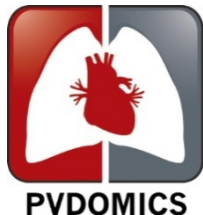


PVDOMICS Study

Collecting Quality Research Data

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NHLBI Pulmonary Vascular Disease Phenomics Program

Funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health with support from the Pulmonary Hypertension Association

General Forms Completion Instructions

- Use a black or blue pen (avoid pens that smear, i.e., gel pens, etc.)
- Write legibly for data entry accuracy
 - Example: a 'Z' can look like the number '2', 'V' can look like 'U'
- Print and capitalize all letters
- Enter only one character or number on each dash



15. Total distance walked (meters)..... 25.

- Use only dashes provided on form -do not add extra dashes
 - Use decimal place provided on form-do not switch decimal placement or add decimal if not there already
 - Each categorical item has assigned code; transcribe code on form
 - Example: 0=No, 1=Yes
- a. Chest pain (0=No, 1=Yes)..... 0

General Forms Completion Instructions

- Dates should always be entered as 'mm/dd/yyyy'
- Fill out top of each page on Form:

Revision of 10/11/2016 PID _____ AC _____ Date of Visit ____/____/____

Form #133
Page 2 of 2

Correcting Errors:

- Do not write over incorrect value:

c. Did participant take a beta-blocker (BB) and/or calcium-channel blocker (CCB) prior to 6MWT? (0= No, 1= Yes)

- Do not use white out

3=Yes, but will need to use a mobility device such as cane, crutches

b. If 5a=3, type of walking aid used

1=Cane/arm-assist cane

4=Rollator (rolling walker)

- Correct error: draw line through incorrect value, write correct value next to old value, date and write initials in margin

9. Type of pulse oximetry probe used? (1=Finger, 2=Ear, 3=Forehead)

10. Room air oxygen saturation at rest (%).....

Source Documentation

- Snap shot on the day of the visit, at time testing was done
- Historical data is hard to reproduce
- Used for data verification: DCC Inquiries, Site Visits
- Best to take source document and copy results to CFR
- Forms where we expect to see source documentation:

Consent Form
Participant Contact Info and Pre-Screen
F103-Non-PVD Comorbid, Med/Surg Hx
F104-Demo, Employment and Income
F110-PH and Medications
F120-Vital Signs Form
F152-CC Sleep Download/Transmittal
F155-CC Hx Sleep Rept Transmission
F200-Ctr CBC w Diff Results
F201-Ctr CMP
F202-Ctr Antinuclear Antibody (ANA)
F203-Ctr HIV Antigen/Antibody Screen
F204-Ctr Hepatitis Screen
F205-Ctr Prothrombin Time (PT)

F206-Ctr Pregnancy Test Results
F207-Ctr ABG Results
F245-Ctr ECG Transmittal
F250-ECHO Transmittal
F251-Cardiac MRI Transmittal
F252-Ctr Chest CT Scan Transmittal
F253-Ctr Hx Chest CT Data Transmittal
F254-V/Q Lung Report Transmittal
F270-Pulmonary Function (PFT) Form
F271-Historical PFT
F280-Right Heart Cath (RHC)
F290-Ctr Non-Invasive CPET
F291-Ctr Invasive CPET
F401-Detailed Adverse Events
F402-Event Inform Sent to the DCC