

L-PVDOMICS PROTOCOL Changes from April 25, 2019 for Version 1.1 September 10, 2019

3.2 Exclusion criteria

Definition of Level of participant is given in Section 4.1.

Participant Level 1:

- Transplant other than heart or lung
- In the clinician's opinion, too ill to perform L-PVDOMICS testing even if limited testing. ~~Not applicable for transplant participants.~~
- Participants who withdrew from the parent PVDOMICS study
- Pregnant or nursing
- Concurrent participation in any investigational drug study or other clinical trial

Participant Level 2:

- Transplant other than heart or lung
- Participants who withdrew from the parent PVDOMICS study

Participant Level 3:

- Participants who withdrew from the parent PVDOMICS study

4. Data Collection

4.1. Study Visit

Level 1 Participation (preferred)

12. If patient had testing (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, ~~ECG-V/Q scan~~) within 3 months (either side) of follow-up visit, include clinically available data.

Level 2 Participation

12. If patient had testing (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, ~~ECG-V/Q scan~~) within 3 months (either side) of follow-up visit, include clinically available data.

Level 3 Participation

April 25, 2019 Version:

If PVDOMICS participant had a lung or heart transplant or died since the parent study, the date of transplant or death will be documented per the parent PVDOMICS protocol. For L-PVDOMICS a medical record review will collect clinically available data (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, V/Q scan) from the parent study up to the transplant or death date.

Changed to September 10, 2019 Version 1.1:

Tracked changes:

~~Any person not agreeing to participate at Level 1 or 2 can participate at Level 3. If PVDOMICS participant had a lung or heart transplant or died since the parent study, the date of transplant or death will be documented per the parent PVDOMICS protocol.~~ For L-PVDOMICS this level, a medical record review will collect clinically available data (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, ECG/V/Q scan) within 3 months (either side) of L-PVDOMICS enrollment date. If the ~~PVDOMICS~~ participant had a ~~lung or heart~~ transplant or died since the parent study, the date of transplant or death will be documented per the parent PVDOMICS protocol and the medical record review will collect data from the parent study up within 3 months prior to the transplant or death date.

Untracked changes:

Any person not agreeing to participate at Level 1 or 2 can participate at Level 3. For this level, a medical record review will collect clinically available data (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, ECG) within 3 months (either side) of L-PVDOMICS enrollment date. If the participant had a transplant or died since the parent study, the date of transplant or death will be documented per the parent PVDOMICS protocol and the medical record review will collect data within 3 months prior to the transplant or death date.

4.2.3 Comorbid Conditions since Completion of Parent PVDOMICS Study

Tobacco use (current, total pack years)

Alcohol use (Current, number of drinks per week),

Diabetes Type I, Type II, therapy (diet, oral agent, insulin)

Sleep disordered breathing (current type of treatment)

Hypertension (medications)

Cardiac diagnoses (arrhythmias, valve disease, rheumatic disease, CAD, etc.)

Pulmonary diagnoses

Renal insufficiency (medications)

Liver disease

Obesity

Recent diet or methamphetamine drug exposure (name of medication and year(s) of exposure)

Malignancy aside from localized non-melanoma skin cancer

Exposure to chemotherapeutic drugs (e.g., cyclophosphamide, multi-tyrosine kinase inhibitors)

~~Chest radiation~~

High altitude exposure (duration)

Estrogen containing medication exposure (duration)

DVT or PE or hypercoagulability

Relevant surgical history since completion of parent PVDOMICS study:

- Cardiac surgery (type)

- Atrial septostomy

- Pulmonary surgery (type)

- Gastric bypass or banding

- Pacemaker

- Defibrillator

Added to September 10, 2019 Version 1.1:

4.2.8 Sleep Study

Investigators are encouraged to obtain a Nox3 sleep study to be performed within 6 weeks of enrollment in the L-Omics project (Level 1). If the Nox3 sleep study cannot be obtained, then overnight oximetry is encouraged in the patient's usual sleep setting (i.e., room air, CPAP, BIPAP, O2).

6. Regulatory Considerations

These are unchanged from the parent PVDOMICS protocol for ~~including~~ IRB, confidentiality, participant consent, ~~adverse events, CT scan incidental findings~~ and the Observational Safety and Monitoring Board. However, for the longitudinal study, adverse events will be collected only for Level 1 participant events that occur during the Six Minute Walk test.