

Chapter 232. Transferring Level 2 Enrollees into Level 1 Participants (L2-to-L1)

232.1 Overview

This MOP Chapter 232 only addresses those Level 2 participants who agreed to participate in L-PVDOMICS with the intent to participate as Level 1 at a future time.

On March 20, 2020, the PVDOMICS Steering Committee proposed a plan on how the L-PVDOMICS Study will address the effects of COVID-19 on study operations due to stopping of research visits in all 7 clinical centers. On March 25, 2020, the Observational and Safety Monitoring Board (OSMB) approved the study's plan to enroll eligible Level 1 participants as Level 2 into the L-PVDOMICS study initially but later allow transfer of those Level 2 participants into Level 1 once each clinical center is allowed to resume research visits.

232.2 General Considerations

MOP Chapter 231 reviews how each center must receive approval from their local institution prior to seeing research participants for L-PVDOMICS Level 1 at a clinical visit.

Please review MOP Chapter 231 that addresses how to conduct Level 1 visits within the COVID-19 guidelines established by your institution.

Eligibility:

- 1) This participant **must have been eligible for Level 1** originally but was enrolled as Level 2 on or after March 16, 2020 and prior to a site's approval to re-start enrolling Level 1 subjects.

Note: Level 2 participants enrolled **after the re-start** of Level 1 participants at a given institution cannot be transferred to Level 1 status.

Exclusions from Level 1 participation:

- In the clinician's opinion, too ill to perform L-PVDOMICS testing even if limited testing.
- Pregnant or nursing
- Concurrent participation in any pulmonary hypertension investigational drug study or other blinded placebo-controlled drug clinical trial

- 2) Participant must answer COVID-19 related-questions in accordance with local guidelines and those questions requested for the L-PVDOMICS study. **See MOP Chapter 231, Section 231.2** for detailed information on eligibility for Level 1.

- 3) Participant must sign a new L-PVDOMICS Study consent form to participate as a Level 1 participant (even if your IRB does not require it. A Biobank consent form will need to be signed by the participant.

4) A Form 501 must be completed and entered. This form is specific to L2-to-L1 transfers. Do not complete a Form 500.

232.3 Level 1 Clinical Visit

Please review MOP Chapter 231 that addresses how to conduct Level 1 visits (within the COVID-19 guidelines established by your institution).

In addition to other data collection described in protocol, the in-center Level 1 visit includes the following:

1. Vital Signs - (Form 521)
2. Waist/Hip measurements (Form 531)
3. Height and Weight (Form 532)
4. Six Minute Walk Test (6MWT) (Form 533)
5. Sleep Study (Forms 550, 551, and 552)
6. Echocardiogram (clinical standard-of-care/or research study for disease subjects, and disease comparators) (Form 620)
7. Clinical blood draw – CBC with diff, metabolic panel (Forms 600, 601)
8. Biospecimen Blood and Urine Collection (Forms 800, 820)

Forms identified in Table 1 below will need to be reviewed with the participant to identify any new information. Also, review medical records within 3 months following L2-to-L1 enrollment.

232.5 Documentation of COVID-19 Status

Documentation of COVID-19 is described in MOP Chapter 231 and is repeated here for convenience.

Any new Level 1 participant who develops symptoms of COVID-19 or has a positive COVID-19 nasal swab by PCR within two weeks after biorepository collection should give details on the new COVID-19 form.

Note the following: A person who has had COVID symptoms PRIOR to enrolling in L-PVDOMICS study can only be enrolled as a Level 2 or 3. See section MOP 231.2. Symptoms can be reported on Form 590.

If a participant does not enroll in L-PVDOMICS study, report COVID testing and symptoms on Form 187-Annual Follow-up.

232.6 How to Transfer Eligible Level 2 Participants to Level 1

Participants who completed Level 2 visits in L-PVDOMICS due to COVID-19 restrictions but are willing and eligible to transition to Level 1 enrollment will need to sign a new consent for a Level 1 visit along with Biobank consent form along with documentation of this. Form 501 should be completed and must include the date the consent form was signed as well as the signing of the Biobank consent.

Minimum Level 1 PH/Comparator initial eligibility requires that the participant must have had an echocardiogram and OMICS blood collections 1 and 2 completed in the parent study. If a participant consents to Level 1 participation, a Biorepository Kit number must be available at time of enrollment.

If **ONE month** has passed since the participant was enrolled as a Level 2, the following forms will need to be re-reviewed with the participant for any changes or to add new information. (As stated previously, medical records within 3 months post L2-to-L1 enrollment should be reviewed.)

Table 1. L2 to L1 Forms That Need to be Updated

L-PVDOMICS Study Forms That Will Need To Be Reviewed and Updated, if form was completed more than <u>one</u> month from L2 enrollment	
502	PH Assessment Any new medical issues not previously identified?
503	Non-PVD Comorbidity, Medical and Surgical History Form Any new other medical issues?
505	Exposure History Form Any new exposures?
510	PH and Concomitant Medications Form Any medications newly prescribed, stopped
521	Female Reproductive History Form Any new issues?
532	Measured Height and Weight
570	SF-36 Survey Instrument (SF-36v2)
571	Minnesota Living With Heart Failure® Questionnaire (MLHF)
572	emPHasis-10 Quality of Life