

Chapter 231. Level 1 Participant Visits During COVID-19 Pandemic

231.1 Overview

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus causes the disease called the coronavirus disease 2019 or COVID-19. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. As such, face-to-face research activities for the L-PVDOMICS Study, including sample collection and processing, were suspended for Level 1 participants on March 16, 2020.

The L-PVDOMICS research activities will resume in accord with each research institution's guidelines and with the following considerations. Each institution will need to complete a 'restarting' survey prior to resuming Level 1 visits. Responses to the surveys may be shared with NHLBI Program Office and the OSMB.

Converting Level 2 participants enrolled during the pandemic restrictions to Level 1 participants is outlined in L-PVD MOP Chapter 232.

231.2 General Center Preparation Considerations Prior to Resuming Level 1 Visits

Each center must receive approval from their local institution prior to seeing research participants for L-PVDOMICS Level 1 visits, Complete Center Form 09 to indicate the date that your institution (e.g., IRB, Department) approved enrollment of Level 1 participants for face-to-face visits.

Each site should screen participants for possible COVID-19 as per their institution-specific guidelines. Since each region may experience different rates of infection, the L-PVDOMICS study will allow each site to modify their Level 1 screening to follow their own institutional guidelines. In some cases, COVID-19 testing may be performed in advance of the visit based on institutional policies. For L-PVDOMICS study visits, it is important to contact the participant within 24-hours to ask specific COVID-19 related questions.

If a COVID-19 test is positive by nasal swab by polymerase chain reaction (PCR), the participant should not be enrolled as a Level 1 participant, but could be considered for enrollment as a Level 2 participant. *Note: An antibody test is not specific and not sensitive, and thus cannot be used to determine an individual's COVID positivity.*

If the participant telephone call within 24-hours of a potential Level 1 visit reveals that:

- 1) a participant has had symptoms* regardless of when those symptoms occurred. The participant is excluded from Level 1 and can only be enrolled in Level 2 or 3.

**symptoms are those that a participant may have already have had pre-COVID-19 pandemic (e.g., shortness of breath) but suddenly worsened and/or there was an acute onset of symptoms not previously developed.*

- 2) a participant was exposed to someone with symptoms within the last 28 days but has not developed any symptoms beyond their usual state after exposure. The participant must wait for at least 28 days after the exposure and then will be eligible for Level 1.

Participant Questions

COVID-19 screening should follow standard CDC guidelines and your own institution's requirements.

The five questions listed below are to be asked of potential new L-PVDOMICS Level 1 participants and must be answered on the revised Form 500 (new L1 enrollment). Your institution may require specific questions answered 72 hours in advance of the visit. However, these questions below should be asked the day prior to the Level 1 visit.

If a participant answers 'Yes' to either question #4 or #5 below, the participant should not be enrolled as Level 1. If the participant answers 'Yes' to #1, #2 or #3, the participant should not be enrolled in Level 1 at this time but could be re-considered for Level 1 after at least 28 days have passed.

Alternatively, a participant answering 'Yes' to any of the questions can be considered for Level 2.

1. Have you traveled to an area (such as a 'city' or 'county') that is currently experiencing a higher level of COVID-19 or surge or outbreak as defined by (federal, state or local) guidelines within the last 14 days?

Study Team instructions: Use your institution's guidelines to minimize risk and use best judgement when bringing in a participant for a visit, especially if your area is currently experiencing a surge or higher level of COVID-19 cases. For example, if a participant is from a rural area and you want them to travel to your medical facility that is experiencing a surge, you may need to postpone the visit if they need to stay overnight.

2. Have you or someone close to you been in close contact with a participant with known COVID-19 within the last 28 days?
3. Has a medical professional asked you or someone close to you to self-quarantine within 28 days? Or have you (the participant) begun self-quarantine within the last 28 days based on any exposure you may have encountered.
4. Have you tested positive for COVID-19 in the past 28 days? If so when?
5. Have you experienced any of the following symptoms within the past 3 days that are beyond your usual state: fever, shortness of breath, cough, fatigue, diarrhea or acute loss of taste

and/or smell? That is, your symptoms may already exist but have worsened and/or new symptoms have developed within the past 3 days.

Study Team instructions: The Biorepository Core lab will require the L-PVDOMICS questions be answered again two weeks post-blood collection for safety purposes for those handling so you can tell the participant to expect to hear from you.

231.3 Cleaning and Storage of Equipment Used for Level 1 Testing

Ensure proper procedures are followed for cleaning and storage of equipment before and after participant visits as per your institution's guidelines since the start of the COVID-19 pandemic.

A. Sleep Study Equipment Cleaning

The Sleep Study Core provides detailed instructions on study personnel safety along with care and cleaning of equipment. See MOP Chapter 241 on the L-PVDOMICS website for this document. The URL is:

https://lriapps.ccf.org/pvdomics/open_web/LMOP/LPVD_MOPChap241App5.pdf

B. 6 Minute Walk Test (6MWT) Equipment Cleaning

There are no special disinfecting changes needed. Equipment used for the 6MWT such as the cords, should be cleaned with alcohol pads or purple top wipes after every participant as per the parent study and MOP Chapter 241. Follow your institution's guidelines if additional cleaning procedures are necessary.

C. Vital Sign and Waist/Hip Test Equipment

Please follow guidelines provided by your institution in regards to cleaning multi-use medical equipment after each participant since the start of the COVID-19 pandemic.

D. Echo

Confirm with your local Echo Lab how they will handle Level 1 L-PVD participants and follow guidelines provided by your institution.

231.4 Biorepository Sample Collection, Processing

See Biorepository Chapter 233. The URL is:

https://lriapps.ccf.org/pvdomics/open_web/LMOP/L_PVDMOPChap233-Draw.pdf

Biospecimens from all Level 1 participants will be handled separately when they arrive at the Biorepository Core. To facilitate this process, all sites who send participant samples must provide responses to the questions on F800 and F820 - Biospecimen Collection and enter these forms into the database as soon as possible. The DCC requires that all sites complete a telephone call with each participant 2 weeks after biospecimens are collected regarding symptoms development and/or development of COVID-19 positive status. A separate new COVID form will be created to document this telephone call. This call should be approved by the local site IRB (as it is not specified in the protocol or consent).

This phone call does not mean for the centers to hold on to the biospecimens, rather, it helps the Biorepository Core in processing each sample. Thus entering forms in the database right away are very important.

231.5 Documentation of Positive COVID-19 for Level 1

Any new Level 1 participant who develops symptoms of COVID or has a positive COVID nasal swab by PCR within two weeks after biorepository collection should give details on the new COVID 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 231.2 and symptoms can be reported on Form xxx. If a participant does not enroll in L-PVDOMICS study, report COVID testing and symptoms on Form 187-Annual Follow-up.