

L-PVDOMICS Main Consent Form Template Changes from April 25, 2019 to September 10, 2019

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c) Level 3 Participation

The Level 3 participation is for any individual not agreeing to participate at Level 1 or Level 2. We will review your medical record and extract available information for the study.

Deleted: those

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Added:

Sleep Study

Based upon investigator discretion, you may have an overnight sleep monitoring test. In this case, you will be given a small device to take home, and at bedtime you will wear straps around your chest and abdomen, a small clip on your finger, sensors on your chest for heart monitoring (electrocardiogram) and small plastic prongs in your nose. These will monitor your breathing and oxygen levels while you sleep. We will have you fill in a brief questionnaire asking about your sleep. The following morning you will remove the equipment and return it to the study team.

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Confidentiality Risk

Paragraph 2:

Tests performed at your center, such as laboratory tests, echocardiogram, sleep study results and 6-minute walk test are likely to be placed into your medical record which can be accessed by healthcare providers other than study physicians.

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PRIVACY AND CONFIDENTIALITY

Paragraph 6:

Tests, such as laboratory tests, 6-minute walk, sleep study results and imaging tests like echocardiogram or lung CT scan, are likely to be placed into your medical record at the site of your testing. Placement into your medical record means that healthcare providers outside of the L-PVDOMICS Study, and insurers, will have access to those test results. Placement in medical records also means that any abnormal findings from those tests can be seen by your healthcare providers.