



L-PVDOMICS STUDY

Study Enrollment Form #500

Instructions: Form 500 is completed and entered for each participant who enrolls in the L-PVDOMICS study. The PID and alphanumeric code will be the same as the initial enrollment in the parent study. You will not be able to enter the Form 500 if the participant is not eligible.

Level 1 participation will always require written consent. However, Participation in Levels 2 and 3 is mandated by your local IRB as to whether or not consent to enroll in L-PVDOMICS must be a signed consent form or a verbal agreement is adequate.

Minimum Level 1 PH/Comparator participation requires that participant must have had a right heart catheterization (RHC), echocardiogram and OMICS blood collections 1 and 2 completed in the parent study. (Healthy controls in the parent study did not have RHC.)

If a participant consents to Level 1 In-Person Visit(s):

- 1) A potential Level 1 participant must be screened for COVID-19. A Form 499-COVID-19 Screening must be completed and entered within 72 hours of enrolling. You will not be able to save this Form 500 until Form 499 was saved in the database. If date of screening is greater than 72 hours of enrolling, the participant must be re-screened and a new F499 must be entered.
- 2) a Biorepository Kit number must be available at time of enrollment. You will not be able to save this form unless kit # is recorded in Q9.

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1. Identification Number

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2. Alphacode

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3a. Date of L-PVDOMICS enrollment (mm/dd/yyyy)

- 3b. Was this participant screened for COVID-19 and a Form 499 completed? ____
 0=No, participant is only eligible for Level 2 or Level 3 or participant only agrees to L2 (or L3) (skip to Q4)
 1=Yes, participant agrees to Level 1 (in-person) visit(s). Participant was screened for COVID-19 and a Form 499 was entered into the database.

If Race and Hispanic or Latino ethnicity was 'Unknown or Not reported' during parent study enrollment and participant is willing to provide that information now, please complete Q4 & Q5.

4. For NIH: Hispanic or Latino ethnicity? ____
 0=No, 1=Yes, 9=Unknown or not reported
5. Race? (NIH format – Hispanics must choose a race) ____
 1=American Indian/Alaska Native 5=White
 2=Asian 6=More than one race
 3=Native Hawaiian or Other Pacific Islander
 4=Black or African American 9=Unknown or not reported
6. Current household zip code (if deceased, record last known zip code) ____
7. a. Which study level did the participant agree to? (1=Level 1, 2=Level 2, 3=Level 3) ____
 1=Level 1: in-person study visit at clinical center, Echo, OMICS blood draw, local labs, and other measurements, medical record review
 2=Level 2: agreed to phone visit to review medical status, any hospitalizations and completion of HRQOL documents
 3=Level 3: transplant status, medical record review
- b. Type of consent given ____
 1=Written, required for Level 1
 2=Verbal
 3=Via parent study consent (for participants who died or received heart or lung transplant after parent study protocol period)

8. If Q7b = 1 or 2, date participant signed/agreed to participate in the L-PVDOMICS study? (mm/dd/yyyy) _____/_____/_____
If Level 2 verbal consent or Level 3 participation, skip to the end of this form.

LEVEL 1 Participation Only

Place kit number label here.
Enter the kit number in the
database.

9. Biorepository Kit Number
(Center number is first two digits, LPVD=L-PVDOMICS
the last three digits are sequentially assigned)
10. a. If response was Level 1 participation, did participant agree to be contacted if clinically relevant genetic results become available? (0=No, 1=Yes)
b. If yes to Q10a, what did the participant agree to?
1=ONLY results related to pulmonary hypertension risk
2=ONLY results related to risks for other serious health conditions
3=ANY results related to pulmonary hypertension or other diseases
11. a. Did participant sign L-PVDOMICS Biobank consent form?
0=No
1=Yes, and agreed to allow samples/data to be sent to the Biobank at the end of the L=PVDOMICS study,
2=Yes, but did not agree to allow samples/data to be sent to the Biobank at the end of the L=PVDOMICS study
b. Date participant signed the consent form for the
L-PVDOMICS Biobank? (mm/dd/yyyy)....._____/_____/_____
12. Did Level 1 participant agree to have contact information given to other investigators?
0=No, did not agree to have contact information given out
1=Yes, agreed to have contact information given to other investigators
13. In the clinician's opinion, participant **is able** to perform complete testing according to protocol criteria? (0=No, not eligible for Level 1; 1=Yes, eligible for Level 1)
14. In the clinician's opinion, **too ill** to perform the protocol testing?
(0=No, eligible for Level 1; 1=Yes, not eligible for Level 1)
15. Has received a heart or lung transplant?
(0=No, eligible for Level 1; 1=Yes, not eligible for Level 1)
(Note: a corneal transplant does not exclude participant from Level 1 testing)
16. Is pregnant or nursing? (0=No, eligible; 1=Yes, not eligible for Level 1)
17. Is currently participating in any investigational drug study or other clinical trial? (0=No, eligible for Level 1; 1=Yes, not eligible for Level 1)

200. Date form completed (mm/dd/yyyy)....._____/_____/_____
201. Username of person completing/reviewing completeness of this form.....

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ____/____/____

Username of person entering this form _____