



PVDOMICS STUDY

Center Study Completion and Forever Missing Data

Form #420*

Instructions: This form is completed once per participant when it has been determined by the clinical center that all data within the study period that will ever be collected has been entered into the database.** Refer to detailed report prepared for each participant titled 'Participants with All Completed Forms as of [date]' prior to completing this form. (This report is also known as the 'Smiley Face' report.) There are two pages per participant.

Saving Form 420 in the database will trigger an email message to the DCC for review and authorization of reimbursement which is dependent on data completeness and quality.

If anything on this Form 420 needs to be changed after the form is already entered and saved, the **DCC will delete this form** and the Form 420 should be re-entered with the correct data.

****Form 187 – Annual Follow-up is a stand-alone form and is not reported on this Form 420.**

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1. Identification Number

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2. Alphacode

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3. Center final data review date (mm/dd/yyyy)

4. Participant final PH assessment status as determined on Form 102
 (Auto populated by database: 1=Control, 2=Comparator, 3=PH)

5. Gender (Auto populated by database from Form 100: 1=Male, 2=Female)

Form #	Abbreviated Form Name	Notes	Form Forever Missing? (1=Yes only if form is forever missing; otherwise leave blank)
100	Initial Enrollment		n/a
102	PVD Assessment		___
103	Comorbid, Med/Surg Hx		___
104	Demographics		___
105	Exposure History		___
106	Thrombophilia Hx Form		___
107	Family Hx of PH		___
110	PH and Concomitant Meds		___
120	Study Visit Vital Signs		___
121	Female Reproductive Hx	Not applicable if male participant	___
131	Waist/Hip Measurements		___
132	Height, Weight, and BIA		___
133	6 Minute Walk Test (6MWT)		___
150	Sleep Initial, Demo, Placed		___
151	Sleep Questionnaire	Not expected if Sleep Study using PVDOMICS protocol was not done	___

Form #	Abbreviated Form Name	Notes	Form Forever Missing? (1=Yes only if form is forever missing; otherwise leave blank)
152 <u>or</u> 155	Sleep Download/Transmit <u>or</u> Alternative Sleep Study Transmit	One F152 or F155 is expected per participant	_____
170	SF-36 QOL		_____
171	MLHF QOL		_____
172	emPHasis 10 QOL		_____
185	2-Week Post Assessment	Expected AFTER local IRB approved form	_____
200	CBC w Diff Results		_____
201	CMP Results		_____
202	ANA Results		_____
203	HIV Result		_____
204	Hepatitis Result		_____
205	PT Result		_____
206	Pregnancy Result	Not applicable if male participant	_____
207	ABG Results		_____
245	ECG Transmittal		_____
250	ECHO Transmittal		_____
251	MRI Transmittal		_____
252 <u>or</u> 253	Chest CT Scan Transmit or Hx Transmit	One F252 or F253 is expected per participant	_____
254	V/Q Report Transmittal	Not expected if CTA done or a Control	_____
270 <u>or</u> 271	PFT or Hx PFT	One F270 or F271 is expected per participant	_____
280	RHC (includes resting)	Not expected if a Control	_____
290 <u>or</u> 291	CPET or iCPET	One F290 or F291 is expected per participant	_____
300	Blood Coll. 1 – Drawing		_____
301	Blood Coll. 1– Processing	Not expected if C1 blood was not collected	_____
304 <u>or</u> 307	Blood Coll. 2 – Draw Samples		_____
305 or 308	Blood Coll. 2 – Process PAXgene Sample	Not expected if C2 blood was not collected	_____
306 <u>or</u> 309	Blood Coll. 2 – Process Samples into Cryovials	Not expected if C2 blood was not collected	_____
320	Urine Collection		_____
321	Urine Process Sample	Not expected if urine was not collected.	_____
330	Specimen Storage Log- • Collection 1 • Collection 2	Storage log not expected if blood collection not done	_____ _____

6. **OMICS Biosamples:** Were all of this participant's collected biosamples received in the Biorepository? (0=No, 1=Yes) (Review QC Inventory Report)....._____

7. **Adverse Events:** If there were adverse events reported for this participant on Form 400, were corresponding Form 401's completed for each one? (0=No, 1=Yes, 8=Not applicable)....._____

8. **Incidental Findings:** If there were incidental findings reported by any of the Cores, was a Form 138 completed for each time an email notification was sent to your site for this participant? (0=No, 1=Yes, 8=Not applicable) _____
9. Comments provided to DCC that may help explain why test components and/or data are incomplete? (0=No, 1=Yes) _____

Comments (entered into database)

Note that these codes were removed from Form 412-DropOut and reported here. This is because in many cases there are data collected and may be used in analyses. Any data collected should be entered as your center may be compensated in part for some of these data.

10. a. Based on comments above, please provide primary reason that best explains reason for missing data, if appropriate _____
- 2 = Participant injured himself/herself such that participant could not recuperate in time to complete the study. Center did not complete an extension request.
 - 3 = Participant did or will move away from the Center such that he will not be able to return and complete PVDOMICS study visits.
 - 4 = Participant has changed his mind about PVDOMICS because he does not want to complete right heart catheterization (RHC) even after Study PI talked with participant.
 - 5 = Participant received a transplant (*Do not include corneal transplant*). Report details on Forms 400/401.
 - 6 = Participant became pregnant
 - 8 = Participant withdrew from active participation but will still allow passive data collection which includes review of medical records, keeping samples in Biorepository, and contact for vital status
 - 10 = Participant's PVDOMICS Study participation requires an indeterminate delay because specific testing cannot be done at this time (such as RHC)
 - 11 = Participant refused to have OMICS blood 1 and blood 2 collection done due to concerns with amount of volume collected
 - 12 = Participant progressed to ESRD and is now on dialysis

(If a new reason is identified, notify the DCC via e-mail at pvd-DCCclin@ccf.org and a new code will be assigned.)

100. Username of PI* who attests that study components are completed to the best of the center staff's knowledge and that all data are entered in the database _____

*(*There should be a Form 10 entered into the database.)*

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 _____