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PVDOMICS STUDY FORMS and DATA TRANSMISSION FORMATS TABLE OF CONTENTS – as of 02/08/2024		
Form #	**Version Date***	**Form Name**
CENTER PARTICIPANT FORMS		
100	10/25/2017	Initial Enrollment Form (includes *Inclusion and Exclusion Review* questions)
102	08/03/2021 08/03/2021	PVD Assessment Form 102C-Comparators Only Assessment
103	10/30/2018	Non-PVD Comorbidity, Medical and Surgical History Form
104	04/04/2016	Demographics, Employment and Income Form
105	08/23/2018	Exposure History Form
106	11/09/2017	Thrombophilia History Form
107	06/17/2021	Review of Family History of Pulmonary Hypertension Form
110	06/23/2017	PH and Concomitant Medications Form
115	05/08/2019	Functional Class
120	06/23/2017	Study Visit Vital Signs Form
121	02/21/2018	Female Reproductive History Form
131	07/20/2017	Waist/Hip Measure Form
132	06/08/2017	Height, Weight, and Bioelectrical Impedance (BIA) Form
133	06/15/2018	6 Minute Walk Test (6MWT) Form
150	01/10/2019	Clinical Center Participant Initial Sleep Form
151 151Admin	09/19/2016 11/29/2017	Participant Sleep Study Questionnaire Administration Form for Sleep Study
152	01/10/2019	Clinical Center Sleep Download and Transmittal Form
155	04/04/2018	Clinical Center Alternative Sleep Study Report Transmission Form
170E	05/25/2016	Survey Instrument (SF-36v2) Form – English (administration form included at end of document)
171E	04/05/2016	Minnesota Living With Heart Failure® Questionnaire (MLHF) – English (administration form included at end of document)
172E	04/08/2016	emPHasis-10 Quality of Life Form – English (administration form included at end of document)
185	10/01/2018	Participant Two-Week Event Assessment
187	01/09/2023	Annual Follow-up
200	08/22/2017	Center CBC w Diff Results
201	01/11/2018	Center Complete Metabolic Panel (CMP) Results
202	09/17/2019	Center Antinuclear Antibody (ANA) Results
203	06/23/2017	Center HIV Antigen/Antibody Screen Result
204	02/23/2018	Center Hepatitis Screen Result
205	06/23/2017	Center Prothrombin Time (PT) Results
207	11/10/2017	Center Arterial Blood Gases (ABG) Results
245	01/20/2017	Center Electrocardiogram (ECG) Data Transmittal Form
250	02/27/2019	Echocardiogram (ECHO) Transmittal Form
251	08/31/2017	Cardiac MRI Transmittal Form
252	02/22/2018	Center Chest CT Scan Data Transmittal Form
253	07/05/2017	Center Historical Chest CT Data Transmittal Form
254	07/09/2018	Center Ventilation/Perfusion (V/Q) Scan Report

PVDOMICS STUDY FORMS and DATA TRANSMISSION FORMATS TABLE OF CONTENTS – as of 02/08/2024		
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270	10/27/2017	Pulmonary Function Testing
271	10/10/2017	Historical Pulmonary Function Testing
280	02/27/2019	Clinical Center Right Heart Catheterization (RHC)
290	08/01/2018	Center Cycle Ergometer Non-Invasive CPET Procedure Notes
290A	05/24/2018	Addendum to Center Cycle Ergometer Non-Invasive CPET Procedure Notes
291	08/01/2018	Center Cycle Ergometer Invasive CPET Procedure Notes
291A	05/24/2018	Addendum to Center Cycle Ergometer Invasive CPET Procedure Notes
300	02/16/2017	Center Blood Collection 1 – Drawing Samples Form
301	02/16/2017	Center Blood Collection 1 – Processing Samples Form
303	09/21/2017	Center Blood Collection – Shipping of Frozen Cryovials and *PAXgene*® Tubes to Biorepository Form
304	03/03/2020	Center Blood Collection 2 – Drawing "Rest" Samples Form
305	05/23/2018	Center Blood Collection 2 – Processing PAXgene® "Rest" Sample Form
306	05/23/2018	Center Blood Collection 2 – Processing "Rest" Samples into Cryovials Form
307	05/23/2018	Center Blood Collection 2 – Drawing "Rest, Peak and Post" Samples Form
308	05/23/2018	Center Blood Collection 2 – Processing PAXgene® "Rest, Peak and Post" Sample Form
309	05/23/2018	Center Blood Collection 2 – Processing "Rest, Peak and Post" Samples into Cryovials
320	02/16/2017	Center Urine Collection 1 Sample
321	02/16/2017	Center Urine Collection 1 Processing Sample
330	11/01/2016	Center BTS System Specimen Storage Log
335	06/22/2017	Center BTS System ROOM TEMP Specimen Log and Shipment Form
336	11/01/2016	Center BTS System FROZEN Specimen Shipment Log
400	03/22/2018	Event(s) Notification Form
401	07/10/2019	Detailed Adverse Events Form
900	09/15/2021	COVID-19 Vaccination Details Form *Combined PVDOMICS and LPVDOMICS*
DCC CORE FORMS ONLY		
153	04/02/2018	Sleep Core Receipt and QA Review
154	02/08/2018	Sleep Core Incidental Findings
156	11/13/2018	Sleep Core Review of Alternative Sleep Study Form
220	12/20/2019	Clinical Chemistry Core Results Data Transmission
246	08/06/2018	CPC Electrocardiogram (ECG) Core Results Form
260	10/26/2017	ICL Core Echocardiogram (ECHO) Results Data Transmission
261	10/19/2018	ICL Core Cardiac MRI Imaging Results Data Transmission
262	05/14/2020	Lung Imaging Core (CT) Results

PVDOMICS STUDY FORMS and DATA TRANSMISSION FORMATS TABLE OF CONTENTS – as of 02/08/2024		
Form #	**Version Date***	**Form Name**
262A	03/03/2021	Lung Imaging PA Measures
283	08/02/2018	Core Right Heart Catheterization (RHC) Results
292	03/05/2021	CPC CPET Results
355	08/13/2017	Core BTS ROOM TEMPERATURE Specimen Received Log
356	01/24/2018	Core BTS FROZEN Specimen Received Log
357	07/26/2017	Core BTS Room Temperature Processing
358	07/12/2017	Core Room Temperature Log
360	08/22/2019	Core BTS Destroyed Specimen Log
COMMITTEE REVIEW FORMS		
700	02/25/2019	Adjudication Committee Reviewer Form
701	11/08/2018	Adjudication Committee Final Classification

PVD_SCREEN

Revision of 10/25/2017

PVDOMICS

PVDOMICS STUDY
Initial Enrollment Form #100

Instructions: Form 100 is completed and entered for each participant who consents to the PVDOMICS study. The alphacode is populated at the time this form is saved to the database. The identification number (PID) and alpha(numeric) code are unique to each participant and are used on all data collection forms.

ELIGIBLE

Eligible

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of initial enrollment (mm/dd/yyyy)

4. a. Date participant signed the consent form?(mm/dd/yyyy)..... CONSENT_DT

b. Which consent was signed? (1=Main/Comparator, 2=Control)..... CONSENT

b1. If response to Q4b=1, what type of participant is this? (1=Main, 2=Comparator).. MAIN_COMP

c. Did participant agree to be contacted if clinically relevant genetic results become available? (0=No, 1=Yes)..... GENETIC_CONSENT

d. If yes to 4c (and participant is not a control), what did the participant agree to? ..... PARTICIPANT_AGREE

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

5. a. Did participant sign Biobank consent form? (0=No, 1=Yes*)..... BIOBANK

*Participant agreed to allow samples/data to be sent to the Biobank at the end of the PVDOMICS study.

b. Date participant signed the consent form for the Biobank? (mm/dd/yyyy)..... BIOBANK_DT

6. Sex of participant? (1=Male, 2=Female)..... GENDER

7. *For NIH:* Hispanic or Latino ethnicity? (0=No, 1=Yes, 9=Unknown or not reported).. HISPANIC

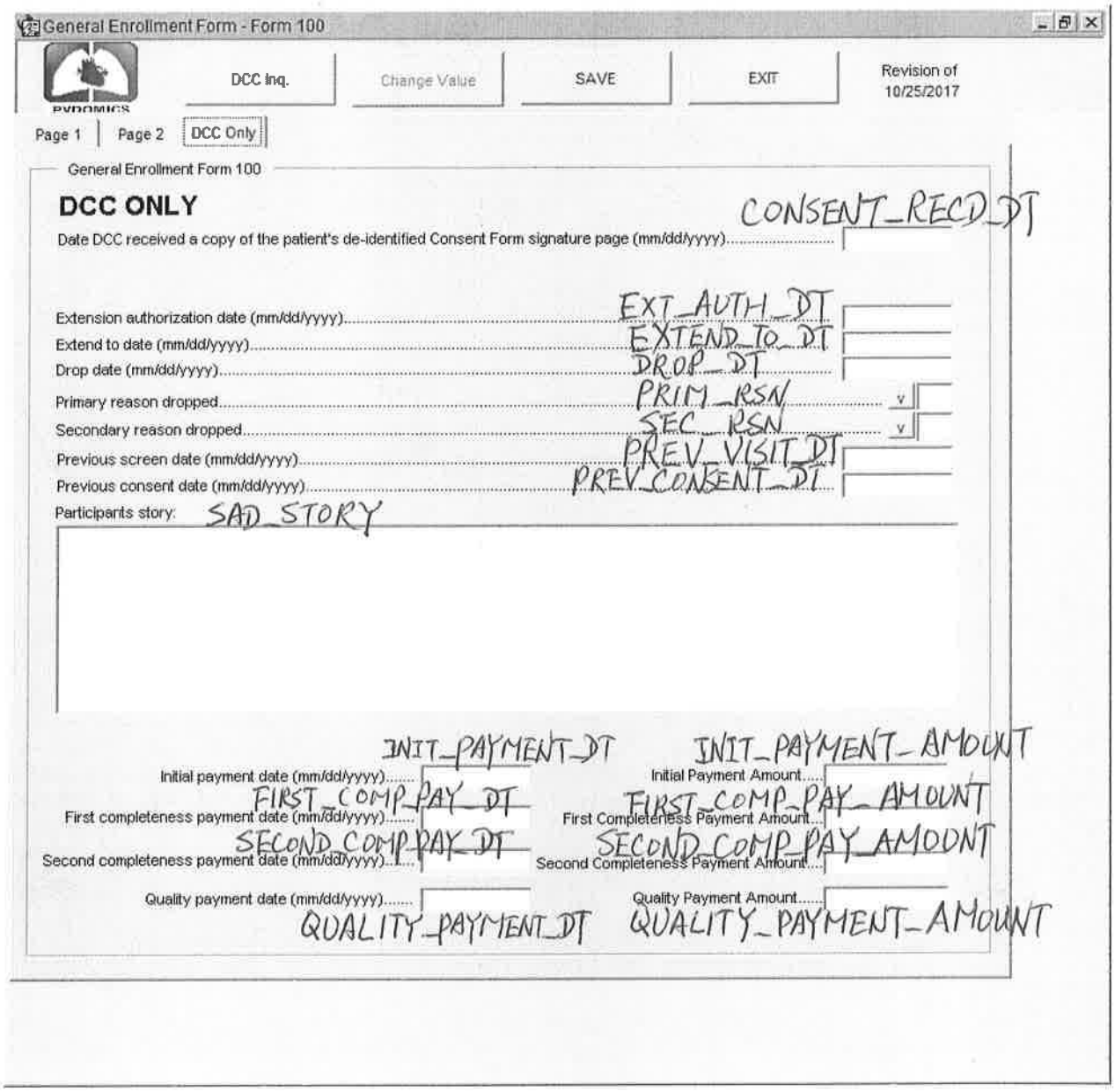
8. Race? (*NIH format – Hispanics must choose a race)*..... RACE

1=American Indian/Alaska Native
2=Asian
3=Native Hawaiian or Other Pacific Islander
4=Black or African American
5=White
6=More than one race
9=Unknown or not reported

9. Date of birth? (mm/dd/yyyy)..... DOB __ __ / __ __ / __ __ __ __

Note, for eligibility, age must be 18 years at the time of enrollment.

(*continued on next page*)


General Enrollment Form - Form 100
DCC Inq.
Change Value
SAVE
EXIT
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Page 1
Page 2
DCC Only
General Enrollment Form 100
DCC ONLY
CONSENT_RECD_DT
Date DCC received a copy of the patient's de-identified Consent Form signature page (mm/dd/yyyy)
EXT_AUTH_DT
Extension authorization date (mm/dd/yyyy)
EXTEND_TO_DT
Extend to date (mm/dd/yyyy)
DROP_DT
Drop date (mm/dd/yyyy)
PRIM_RSN
Primary reason dropped
SEC_RSN
Secondary reason dropped
PREV_VISIT_DT
Previous screen date (mm/dd/yyyy)
PREV_CONSENT_DT
Previous consent date (mm/dd/yyyy)
Participants story:
SAD_STORY
INIT_PAYMENT_DT
Initial payment date (mm/dd/yyyy)
INIT_PAYMENT_AMOUNT
Initial Payment Amount
FIRST_COMP_PAY_DT
First completeness payment date (mm/dd/yyyy)
FIRST_COMP_PAY_AMOUNT
First Completeness Payment Amount
SECOND_COMP_PAY_DT
Second completeness payment date (mm/dd/yyyy)
SECOND_COMP_PAY_AMOUNT
Second Completeness Payment Amount
Quality payment date (mm/dd/yyyy)
QUALITY_PAYMENT_DT
Quality Payment Amount
QUALITY_PAYMENT_AMOUNT

PVD_ASSESSMENT

PVDOMICS

PVDOMICS STUDY
PVD Assessment - Form #102

Instructions: This form is completed and entered for all participants. Database will skip over sections that do not apply.

For Comparators and PH Groups, complete this form after the right heart catheterization and other tests are completed. Use all medical and surgical history related to pulmonary vascular disease (PVD). Information should be obtained from medical records, local physician records, and participant interview. It should include any current diagnoses and past pertinent history.

Medical records might include, but are not limited to: hospital discharge summaries, consultation letters, MD progress notes, problem lists, medication records and imaging reports [i.e. x-ray, ultrasound, CT].

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of review: mm/dd/yyyy

4. Identify PVD status of this participant..... PVD_STATUS
   1=Control, go to Q200.
   2=Comparator, go to Q5.
   3=PH, go to Q11.

COMPARATORS

If Q4=2-Comparator, complete the following items Q5-Q10:

5. Was this participant diagnosed with any of these WHO Group **1** comparator diagnoses? ..... WHO_1_COMP_DIAG
   For Q5: 0=No, skip to Q6; 1=Yes, *complete Q5a-d.*

   For Q5a-d: use 0=No, 1=Yes

   a. Mild PH (mPAP 21 to <25)? ..... PH_MILD
   b. ePAH (exercise mPAP ≥ 30, flow <10 L/min and mPAP-Q slope >3) (mmHg*min/L)..... EPAH
   c. Relative of heritable pulmonary arterial hypertension (HPAH)..... HPAH
   d. CTD with mild (mPAP 21 to <25) or no PH ..... CTD_MILD

6. Was this participant diagnosed with any of these WHO Group **2** comparator diagnoses? ..... WHO_2_COMP_DIAG
   For Q6: 0=No, skip to Q7; 1=Yes, *complete Q6a-b2*

   For Q6a-b2: use 0=No, 1=Yes

   a. Mild PVD risk associated with LHD (left heart disease with mPAP <25)? ..... PVD_MILD_RISK_LHD
   b. Moderate PVD risk associated with LHD with no PVD but meets one of the following criteria? PVD_MILD_RISK_LHD

      b.1. Isolated post-capillary pulmonary hypertension (Ipc-PH) mPAP ≥ 25, PVR <3, DPG <7 (mmHg)? ..... IPC_PH

      Retired: Q6b.2. Provocable mPCW >18 or mPCW >15 with large (> 5 mmHg) v waves following challenge and represents significant change from resting hemodynamics?

6b, continued,

6.b.3. Provocable mPCW >18 following challenge, V waves < 5 mmHg, and represents significant change from resting hemodynamics? (0=No, 1=Yes) MPCW18

6.b.4. Provocable mPCW >15 with large (> 5 mmHg) V waves following challenge and represents significant change from resting hemodynamics? (0=No, 1=Yes) ..... MPCW15 and __

7. Was this participant diagnosed with any of these WHO Group **3** comparator diagnoses? ..... WHO_3_COMP_DIAG
For Q7: 0=No, skip to Q8; 1=Yes, *complete Q7a-f, h-i.*

For Q7a-g: use 0=No, 1=Yes

a. Chronic Obstructive Pulmonary Disease (COPD)? ..... COMP_COPD

b. Idiopathic Pulmonary Fibrosis (IPF)? ..... COMP_IPF

c. Other Interstitial Lung Diseases (ILD) including CPFE and SSc-ILD? ..... COMP_ILD

d. Obstructive Sleep Apnea (OSA)? ..... COMP_OSA

e. Obesity Hypoventilation Syndrome (OHS)? ..... COMP_OHS

f. Sarcoidosis? *(use codes below)* ..... COMP_SARCOIDOSIS
0=No, 1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosis made by biopsy as per protocol

g.Mild to no PVD risk (mPAP <21) or Moderate PVD risk (mPAP 21 to <25)(question retired as of 01/10/2019)

h. Mild to no PVD risk (mPAP <21)? ..... MILD_PVD_RISK

i. Moderate PVD risk (mPAP 21 to <25)? ..... MOD_PVD_RISK

j. Moderate-significant restrictive lung physiology without ILD? ..... RESTRICT_LUNG

8. Was this participant diagnosed with this WHO Group **4** comparator diagnosis? ..... WHO_4_COMP_DIAG
For Q8: 0=No, skip to Q9; 1=Yes, *complete Q8a.*

a. Chronic PE with mild to no PVD (mPAP <25)? (0=No, 1=Yes) ..... CHRONIC_PE

9. What is the Primary WHO Group Comparator classification? ..... COMP_WHO_PRIM

1=WHO Group 1	3=WHO Group 3	5=WHO Group 5
2=WHO Group 2	4=WHO Group 4	

10. What is the Secondary WHO Group Comparator classification? ..... COMP_WHO_SEC

1=WHO Group 1	3=WHO Group 3	5=WHO Group 5
2=WHO Group 2	4=WHO Group 4	8=Not applicable

*If Q5-10 were answered, skip to Q19 – **Comments** for Adjudication Committee*

PULMONARY HYPERTENSION (PH) – Answer Q11-end of form.

11. a. How was participant diagnosed with pulmonary hypertension (PH) at time of enrollment (*Form 100 enroll date*)? ..... PH_DIAG
1=Diagnosed by right heart cath (RHC)
2=Diagnosed by testing but not including RHC
3=PH suspected

5/17/2018 Q12d7-undifferentiated CTD added. 06/28/2018Q14j-cystic fibrosis. 01/10/2019: Q7g. Mild to no PVD risk (mPAP <21) or Moderate PVD risk (mPAP 21 to <25) split into two separate questions. Sarcoid Q7 and 16a response codes added-1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosed by biopsy as per protocol); Q9 & 10: Comparator codes added: 5=WHO Group 5: DCC only 'pure' inquiry number.

b. Was a WHO PH Group previously identified for this participant? PH_WHO_GRP_IDENT
(0=No, skip to 11d, 1=Yes, complete Q11c)

c. If yes, what group? PH_WHO_GRP

1=WHO Group 1
2=WHO Group 2
3=WHO Group 3
4=WHO Group 4
5=WHO Group 5
6=Mixed
9=Unknown

d. Date of PH diagnosis (mm/dd/yyyy) __ PH_DIAG_DT
If day of diagnosis is unknown, insert '15'.

Any of the following PH associated medical conditions:

WHO Group 1 Review – Pulmonary arterial hypertension (PAH)

12. Was this participant diagnosed with any of these WHO Group **1** diagnoses? WHO_GROUP_1
For Q12: 0=No, skip to Q13; 1=Yes, *complete Q12a-j.*

For Q12a-j: use 0=No, 1=Yes:

a. IPAH (Idiopathic pulmonary arterial hypertension)? IPAH
b. FPAH (Familial pulmonary arterial hypertension)? FPAH
b.1. Hereditary hemorrhagic telangiectasia (HHT) HHT
c. Drug-induced pulmonary arterial hypertension? DIPAH
d. Connective tissue disease (CTD)? CONN_TISSUE
d.1. Systemic lupus erythematosus (Lupus) (SLE)? SLE
d.2. Sjogrens? SJOGRENS
d.3. Rheumatoid Arthritis (RA)? RA
d.4. Mixed connective tissue disease (MCTD)? MCTD
d.5. Systemic sclerosis (SSc)? SSC
d.6. Antisynthestase syndrome ANTISYNTH_SYND
d.7. CTD, undifferentiated UNDIFF_CTD
e. Human immunodeficiency virus (HIV) infection induced PH? HIV
f. Portal hypertension PORTAL_HYPER
g. Congenital heart disease (CHD) CHD
g.1 Was the shunt repaired? SHUNT_REPAIR
h. Schistosomiasis? SCHISTOSOMIASIS
i. Pulmonary-capillary hemangiomatosis (PCH)? PCH
j. Pulmonary veno-occlusive disease (PVOD)? PVOD

5/17/2018 Q12d7-undifferentiated CTD added. 06/28/2018Q14j-cystic fibrosis. 01/10/2019: Q7g. Mild to no PVD risk (mPAP <21) or Moderate PVD risk (mPAP 21 to <25) split into two separate questions. Sarcoid Q7 and 16a response codes added-1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosed by biopsy as per protocol); Q9 & 10: Comparator codes added: 5=WHO Group 5: DCC only 'pure' inquiry number.

WHO Group 2 Review – PH due to Heart Diseases

13. Was this participant diagnosed with any of these WHO Group **2** diagnoses? WHO_GROUP_2
For Q13: 0=No, skip to Q14; 1=Yes, *complete Q13a-d.*

For Q13a-d2: use 0=No, 1=Yes:

a. Valvular heart disease? ..... VHD
a.1. Stenotic? ..... STENOTIC
a.2. Regurgitant? ..... REGURGITANT
b. Systolic heart failure? ..... SYS_HRT_FAIL
c. Heart failure with preserved ejection fraction? ..... HRT_FAIL_PEF
d. Cardiomyopathy? ..... CARDIOMYOPATHY
d.1. Hypertrophic? ..... HYPERTROPHIC
d.2. Restrictive? ..... RESTRICTIVE

WHO Group 3 Review – PH due to Lung Disease and/or Hypoxemia

14. Was this participant diagnosed with any of these WHO Group **3** diagnoses? WHO_GROUP_3
For Q14: 0=No, skip to Q15; 1=Yes, *complete Q14a-i.*

For Q14a-i: 0=No, 1=Yes:

a. Chronic obstructive pulmonary disease (COPD)? ..... COPD
b. Idiopathic pulmonary fibrosis (IPF)? ..... IPF
c. Combined pulmonary fibrosis and emphysema (CPFE)? ..... CPFE
d. Other interstitial lung disease (ILD)? ..... ILD
e. Obstructive sleep apnea (OSA)? ..... OSA
f. Non-parenchymal restrictive lung disease (RLD)? ..... RLD
g. Obesity hypoventilation syndrome (OHS)? ..... OHS
h. Hypersensitivity pneumonitis? ..... HYPER_PNEUM
i. Thoracic cage abnormality? ..... THOR_CAGE_ABN
j. Cystic fibrosis? ..... CYSTIC_FIB

WHO Group 4 Review

15. Was this participant diagnosed with any of these WHO Group **4** diagnoses? WHO_GROUP_4
For Q15: 0=No, skip to Q16; 1=Yes, *complete Q15a-c.*

a. Chronic thromboembolic pulmonary hypertension (CTEPH) (0=No, 1=Yes) ..... CTEPH
b. Pulmonary thromboendarterectomy (PTE) (0=No, 1=Yes) ..... PTE
c. Balloon pulmonary angioplasty (BPA) (0=No, 1=Yes) ..... BPA

5/17/2018 Q12d7-undifferentiated CTD added. 06/28/2018Q14j-cystic fibrosis. 01/10/2019: Q7g. Mild to no PVD risk (mPAP <21) or Moderate PVD risk (mPAP 21 to <25) split into two separate questions. Sarcoid Q7 and 16a response codes added-1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosed by biopsy as per protocol); Q9 & 10: Comparator codes added: 5=WHO Group 5: DCC only 'pure' inquiry number.

WHO Group 5 Review

16. Was this participant diagnosed with any of these WHO Group **5** diagnoses? WHO_GROUP_5
For Q16: 0=No, skip to Q17; 1=Yes, *complete Q16a-c2.*

For Q16a-c2: Use 0=No, 1=Yes:

*16*a. Sarcoidosis? *(use codes below)* SARCOIDOSIS
0=No, 1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosis made by biopsy as per protocol

b. Myeloproliferative Disease? MYELOPROLIF_DIS

c. Hemoglobinopathy? HEMOGLOBINOPATHY

c.1. Sickle Cell? SICKLE_CELL

c.2. Thalassemia? THALASSEMIA

---

17. What WHO Group does the PVDOMICS Study Team think this participant falls into **now**? WHO_NOW

1=WHO Group 1
2=WHO Group 2
3=WHO Group 3
4=WHO Group 4
5=WHO Group 5
6=Mixed *(must complete Q17a-c, Q18a-e, and Q19-Comments)*

If response to **Q17=6=Mixed**, please identify WHO Groups using the codes below:

1=WHO Group 1
2=WHO Group 2
3=WHO Group 3
4=WHO Group 4
5=WHO Group 5
8=Not applicable

a. What is the Primary WHO Group classification? WHO_PRIMARY

b. What is the Secondary WHO Group classification? WHO_SECONDARY

c. What is the Tertiary WHO Group classification? WHO_TERTIARY

If Q17 **a and b** = WHO Groups 1 and/or 2 and/or 3, complete Q18:

Note: Participant can only be classified once in Q18a-e:

18. a. Is this participant's PH considered Mixed WHO Groups 2 & 3 as defined below (0=No, skip to 18c, 1=Yes) WHO_PH_MIXED_23

Definition:

•PCW > 18, LAH, LAE, atrial fib **AND**

•COPD, IPF, SSc-ILD, OHS, OSA, non-parenchymal restrictive lung diagnosis or CPFE

b. What is mixed WHO Group for 2 and 3? WHO_MIXED_2_3
1=WHO 2, 3: acute worsening in PCW with fluid challenge, exercise, pulmonary vasodilator
2=WHO 3, 2: acute worsening of oxygenation or only mild elevation of PCW

c. Is this participant's PH considered WHO 1 & 3 as described below (0=No, 1=Yes) ..... WHO_PH_MIXED_1-3

Features of WHO 1: i.e,

- autoimmune serology, positive family history **AND**
- mild (COPD, IPF, SSc-ILD, OHS, OSA, non-parenchymal restrictive lung diagnosis, CPFE); ie. evidence of progressive PH in response to activity and/or over time with stability of hypoxemia or mild parenchymal lung disease

d. Is this participant's PH considered WHO 1, 2 as described below (0=No, 1=Yes) ..... WHO_PH_MIXED_1-2

- WHO 1, 2: PAH (WHO 1, autoimmune serology) with provocation elevation in PCW

e. Is this participant's mixed PH described as 'other'? (0=No, 1=Yes) ..... WHO_PH_MIXED_OTH

Please provide rationale for decision in Comments below.

19. **Comments/Rationale for Adjudication Committee** *(required). Continue on next page, if needed.*
COMMENTS

199. Username of physician reviewing/completing this form ..... PHYS_USERNAME
(Username is the first 6 letters of physician's last name and first initial.)
*This should be the center PI or other study physician trained on the PVDOMICS RHC protocol.

200. Date this form completed (mm/dd/yyyy)..... ____/____/COMP_DT

201. Username of person reviewing completeness of this form..... COMP_USER

Clinical Center Use Only

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

Username of person entering this form___ENTER_USER

DCC Only: *For PH and Comparator WHO Groups*:

DCC Inq # of 'pure' WHO Group assigned but has other 'mixed' WHO Group condition(s):..... INQ_N

DCC Comments DCC_COMMENTS

5/17/2018 Q12d7-undifferentiated CTD added. 06/28/2018Q14j-cystic fibrosis. 01/10/2019: Q7g. Mild to no PVD risk (mPAP <21) or Moderate PVD risk (mPAP 21 to <25) split into two separate questions. Sarcoid Q7 and 16a response codes added-1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosed by biopsy as per protocol); Q9 & 10: Comparator codes added: 5=WHO Group 5: DCC only 'pure' inquiry number.

PVDOMICS

PVDOMICS STUDY
Comparator Additional PH Comorbidities - Form #102C

Instructions: This form is completed and entered for **COMPARATORS** only as per a list distributed by the Data Coordinating Center. The database will skip over sections that do not apply. A physician familiar with PVDOMICS and participant should complete/review this form. The purpose of this form is to collect information on comorbidities not included in the main F102. This will not lead to WHO Group re-classification.

Use all medical and surgical history related to pulmonary vascular disease (PVD). Information should be obtained from medical records, local physician records, and participant interview. It should include any current diagnoses and past pertinent history. Medical records might include, but are not limited to: hospital discharge summaries, consultation letters, MD progress notes, problem lists, medication records and imaging reports [i.e, x-ray, ultrasound, CT].

1. Identification Number **PID**	2. Alphacode **AC**	3. Date of review: mm/dd/yyyy **VISIT_DT**

Any of the following PH-associated medical conditions for COMPARATORS:

COMPARATOR Group 1 Review – Comparator for Pulmonary Arterial Hypertension

4. Was this participant diagnosed with any of these comparator WHO Group **1** conditions? ..... **WHO1_COND** ___
   For Q4: 0=No, *skip to Q5*; 1=Yes, *complete Q4a-k.* For Q4a-k: use 0=No, 1=Yes:
   - a. IPAH (Idiopathic pulmonary arterial hypertension)? ..... **C_IPAH** ___
   - b. FPAH (Familial pulmonary arterial hypertension)? ..... **C_FPAH** ___
     - b.1. Hereditary hemorrhagic telangiectasia (HHT)..... **C_HHT** ___
     Note: for the purposes of this study, PVDOMICS is not differentiating between Familial PAH (FPAH) and Heritable PAH (HPAH)
   - c. Drug-induced pulmonary arterial hypertension? ..... **C_PAH** ___
   - d. Connective tissue disease (CTD)? ..... **C_CONN_TISSUE** ___
     - d.1. Systemic lupus erythematosus (Lupus) (SLE)?..... **C_SLE** ___
     - d.2. Sjogrens?..... **C_SJOGRENS** ___
     - d.3. Rheumatoid Arthritis (RA)? ..... **C_RA** ___
     - d.4. Mixed connective tissue disease (MCTD)? ..... **C_MCTD** ___
     - d.5. Systemic sclerosis (SSc)? ..... **C_SSC_G1** ___
     - d.6. Antisynthestase syndrome ..... **C_ANTISYNTH** ___
     - d.7. CTD, undifferentiated..... **C_UNCTD** ___
   - e. Human immunodeficiency virus (HIV) infection induced PH? ..... **C_HIV** ___
   - f. Portal hypertension ..... **C_PHYPER** ___

g. Congenital heart disease (CHD) ..... **C_CHD** ___

g.1 Was the shunt repaired? ..... **C_SHUNT** ___

h. Schistosomiasis? ..... **C_SHIST** ___

i. Pulmonary-capillary hemangiomatosis (PCH)? ..... **C_PCH** ___

j. Pulmonary veno-occlusive disease (PVOD)? ..... **C_PVOD** ___

k. Other Group 1 condition not listed above? (*Specify Q4k with condition in Comments*) ..... **GROUP_1_OTH** ___

COMPARATOR Group 2 Review – Comparator for Left Heart Diseases

5. Was this participant diagnosed with any of these comparator WHO Group **2** conditions? ..... **WHO2_COND** ___
For Q5: 0=No, *skip to Q6*; 1=Yes, *complete Q5a-e.* For Q5a-d.2: use 0=No, 1=Yes

a. Valvular heart disease? ..... **C_VHD** ___

a.1. Stenotic? ..... **C_STENOTIC** ___

a.2. Regurgitant? ..... **C_REGURG** ___

b. Systolic heart failure? ..... **C_SYSFAIL** ___

c. Heart failure with preserved ejection fraction? ..... **C_HRTFAIL** ___

d. Cardiomyopathy? ..... **C_MYOPATHY** ___

d.1. Hypertrophic? ..... **C_TROPHIC** ___

d.2. Restrictive? ..... **C_RESTR** ___

e. Other Group 2 condition not listed above? (*Specify Q5e with condition in Comments*) ..... **GROUP_2_OTH** ___

COMPARATOR Group 3 Review – Comparator for Lung Disease and/or Hypoxemia

6. Was this participant diagnosed with any of these comparator WHO Group **3** conditions? ..... **WHO3_COND** ___
For Q6: 0=No, *skip to Q7*; 1=Yes, *complete 6a-e.* For Q6a-c, e: use 0=No, 1=Yes

a. Systemic sclerosis (SSc)? ..... **C_SSC_G3** ___

b. Thoracic cage abnormality? ..... **C_THOR** ___

c. Cystic fibrosis? ..... **C_SYSTICFIB** ___

d. Sarcoidosis? *(use codes below)* ..... **C_SARC_G3** ___
0=No, 1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosis made by biopsy as per protocol

e. Other Group 3 condition not listed above? (*Specify Q6e with condition in Comments*) ..... **GROUP_3_OTH** ___

COMPARATOR Group 4 Review

7. Did this participant undergo any of these comparator WHO Group **4** procedures? ..... **WHO4_PROC** ___
For Q7: 0=No, *skip to Q8*; 1=Yes, *complete Q7a-c.* For Q7a-c: use 0=No, 1=Yes
Note: Only history of PTE and/or BPA prior to enrollment or during the 6 weeks of PVDOMICS testing should be reported.

a. Pulmonary thromboendarterectomy (PTE) ..... **C_PTE** ___

b. Balloon pulmonary angioplasty (BPA) ..... **C_BPA** ___

Note for DCC: It is possible for Q5d =1, but Q5d.1 and d.2 = 0 (JL, email, 10/23/2020). 8/3/2021: "Other" added as Q4k, Q5e, Q6e, Q7c, Q8d.

c. Other Group 4 condition not listed above? (*Specify Q7c with condition in Comments*) ..... **GROUP_4_OTH** ___

COMPARATOR Group 5 Review

8. Was this participant diagnosed with any of these comparator WHO Group **5** conditions? ..... **WHO5_OTH** ___
   For Q8: 0=No, *skip to Q199*; 1=Yes, *complete Q8a-d.*

   a. Sarcoidosis? *(use codes below)* ..... **C_SARC_G5** ___
      0=No, 1=Yes, unknown if diagnosis was by biopsy, 2=Yes, diagnosis made by biopsy as per protocol

   b. Hemoglobinopathy? *(use codes below)* ..... **C_HEMOG** ___
      0=No, 1=Yes, Sickle Cell Disease, 2=Yes, Thalassemia

   c. Myeloproliferative disease? *(use codes below)* ..... **C_MYELO** ___
      0=No, 1=Yes

   d. Other Group 5 condition not listed above? (*Specify Q8d with condition in Comments*) ..... **GROUP_5_OTH** ___

9. **Comments for Adjudication Committee** *(required). Continue on next page, if needed.*
COMP_COMMENTS

199. Username of **physician reviewing/completing** this form..... **PHYS_USERNAME** ___ ___ ___ ___ ___ ___ ___
   (*Username is the first 6 letters of physician's last name and first initial.)*
   *This should be the center PI or other study physician trained on the PVDOMICS protocol.

200. Date this form completed (mm/dd/yyyy)..... **COMP_DT** ___ ___/___ ___ /___ ___ ___ ___

201. Username of person reviewing completeness of this form..... **COMP_USER** ___ ___ ___ ___ ___ ___ ___

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ___ ___/___ ___ /___ **ENTER_DT** ___ ___ ___

Username of person entering this form___ ___ ___ ___ ___ ___ ___ **ENTER_USER**

Note for DCC: It is possible for Q5d =1, but Q5d.1 and d.2 = 0 (JL, email, 10/23/2020). 8/3/2021: "Other" added as Q4k, Q5e, Q6e, Q7c, Q8d.

PVD_SURG_HISTORY

PVDOMICS

PVDOMICS STUDY
Non-PVD Comorbidity, Medical and Surgical History - Form #103

Instructions: This form is used to capture all comorbidities, medical and surgical history OTHER THAN pulmonary vascular disease (PVD) which is on Form 102. Information should be obtained from medical records, local physician records, and participant interview. It should include any current diagnoses and past pertinent history.

Medical records might include, but are not limited to: hospital discharge summaries, consultation letters, MD progress notes, problem lists, medication records and imaging reports [i.e. x-ray, ultrasound, CT].

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of visit: mm/dd/yyyy

History of any of the following conditions:
For Questions 4-26: 0=No, 1=Yes, *except where indicated otherwise*

4. In the last 12 months, how many times was the patient admitted to an ICU for > 24 hours (0=Not admitted, 1=Admitted once, 2=Admitted twice 3=Admitted 3 times or more)? ICU
5. Ever been intubated other than for surgery? INTUBATED
6. Myocardial infarction (MI)? (0=No, 1=Yes, answer a & b) MI
   a. Myocardial infarction in past year? MI_WITHIN_1YR
   b. Myocardial infarction > than 1 year? MI_AFTER_1YR
7. Coronary artery bypass grafting or stenting of coronary artery? CAD
8. Atrial arrhythmia? (0=No, 1=Yes, current, 2=Yes, past, 3=Yes, both current and past) ATRIAL_ARRHY
9. History of a cardiac shunt? (0=No, 1=Yes) CARDIAC_SHUNT

   If yes to Q9, code 9a-d: 0=No, 1=Yes
   a. Patent foramen ovale (PFO) SHUNT_PFO
   b. Atrial septal defect (ASD) SHUNT_ASD
   c. Ventricular septal defect (VSD) SHUNT_VSD
   d. Atrial septostomy SHUNT_SEPTOSTOMY
   e. Status of shunt (1=Closed, 2=Not closed, 9=Unknown) SHUNT_STATUS
10. Cerebrovascular/TIA disease? TIA
    a. CVA? (0=No, 1=Yes, without residual deficits, 2=Yes, with residual deficits) CVA
    b. Carotid stenosis? CAROTID_STEN
11. Peripheral vascular disease? PVD
    a. Claudication with medical therapy or stenting or surgery? CLAUD

12. TAA or AAA or dissection? ..... TAA_DISSECT
13. TAA or AAA repair/grafting? ..... TAA_REPAIR
14. Hypertension? ..... HYPERTENSION
15. Diabetes (0=No, 1=Yes, Type 1, 2=Yes, Type 2)? ..... DIABETES

    a. Current diabetes therapy:
    a1. Diabetes controlled by diet only (0=No, 1=Yes) ..... DM_DIET
    a2. Currently taking oral meds (0=No, 1=Yes) ..... DM_OAAL
    a3. Currently using insulin (0=No, 1=Yes) ..... DM_INSULIN

    b. Retinopathy? (0=No, 1=Yes) ..... RETINOPATHY
    c. Neuropathy? (0=No, 1=Yes) ..... NEUROPATHY
    d. Kidney Disease? (0=No, 1=Yes) ..... KIDNEY_DIS
16. Thyroid disease? (0=No, 1=Yes) ..... THYROID_DIS

    a. Hyperthyroidism? (0=No, 1=Yes) ..... HYPERTHYROIDISM
    b. Hypothyroidism? (0=No, 1=Yes) ..... HYPOTHYROIDISM
17. Clinically diagnosed depression? (0=No, 1=Yes, on medication, 2=Yes, not on medication) ..... DEPRESSION
18. Primary biliary cirrhosis (PBC)? (0=No, 1=Yes) ..... PBC
19. History of reactive airway disease? (0=No, 1=Yes) ..... AIRWAY_DIS
20. Hepatitis B surface antigen positive? (0=No, 1=Yes) ..... HEP_B_POS
21. Hepatitis C positive? (0=No, 1=Yes) ..... HEP_C_POS
22. Hepatitis (not otherwise specified, treated or not)? ((0=No, 1=Yes) ..... HEP_NOS
23. HIV (Human Immunodeficiency Virus) infection/AIDs? (0=No, 1=Yes) ..... HIV
24. History of cancer (other than non-melanoma skin cancer)? (0=No, 1=Yes) ..... CANCER
    0=No, 1=Yes, within the past 5 years, 2=Yes, ≥5.0 years

Exercise History:

25. Current exercise frequency (times per week) ..... EXER_FREQ
26. Current usual exercise duration (minutes) ..... EXER_DUR

200. Date this form completed (mm/dd/yyyy) ..... ___/___/COMP_DT
201. Username of person reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ ENTEN_DT

Username of person entering this form ENTEN_USER

10/30/2018 Q25-exercise frequency updated to two spaces.

PVD_DEMO

Revision 04/04/2016

PVDOMICS

PVDOMICS STUDY
Demographics, Employment, and Income Form #104

Instructions: This form is completed one time at the first PVDOMICS visit.

PID | AC | VISIT_DT

1. Identification Number 2. Alphacode 3. Date of visit: (mm/dd/yyyy)

4. Marital status ..... MARITAL ___
   1=Never been married
   2=Married
   3=Common law marriage/partnered/ living together unmarried
   4=Separated
   5=Divorced
   6=Widowed
   9=Unknown or refused

5. Household status ..... HH_STATUS ___
   1=Lives alone
   2=Lives with family (spouse/partner, children, parents)
   3=Lives with others (roommates)
   9=Unknown or refused

6. Highest level of formal education achieved ..... EDUCATION ___
   1=Less than or equal to 8th grade
   2=9th-12th grade, no diploma
   3=High school graduate
   4=Vocational/technical/business
   5=Some college, no degree
   6=Associate degree
   7=Bachelor's degree
   8=Advanced degree
   9=Unknown or refused

7. Participant's primary language? (1=English, 2=Spanish, 8=Other) ..... LANG ___

8. Last year the participant was employed ..... EMPLOYED ___ ___ ___ ___
   (Enter current year if currently employed)

9. Current work status: ..... WORK_STAT ___ ___
   1=Student, not employed
   2=Student, employed
   3=Homemaker
   4=Not working, not seeking work, disabled
   5=Not working, not seeking work, not disabled
   6=Not working, seeking work, disabled
   7=Not working, seeking work, not disabled
   8=Employed full-time
   9=Employed part-time
   10=Retired
   99=Unknown or refused

10. Current household gross annual income (U.S. dollars) ..... HH_INCOME ___
    1=<$10,000
    2=$10,000-$14,999
    3=$15,000-$19,999
    4=$20,000-$29,999
    5=$30,000-$39,999
    6=$40,000-$49,999
    7=$50,000-$99,999
    8=>$100,000
    9=Unknown or refused

11. Number of people considered to be part of this household? ..... HH_NO ___ ___

12. Household zip code ..... HH_ZIP ___ ___ ___ ___ ___

200. Date this form completed (mm/dd/yyyy) COMP_DT __/__/____

201. Username of person completing/reviewing completeness of this form COMP_USER _____

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT _____

Username of person entering this form ENTER_USER _____

Clinical Center = CC_N

PVD_EXP_HIST

PVDOMICS

PVDOMICS STUDY
EXPOSURE HISTORY - FORM #105

Instructions: Review the participant's medical information. Interviewing the participant may also yield additional information regarding current and past exposures.

PID [ ][ ][ ][ ][ ][ ] AC [ ][ ] VISIT_DT [ ][ ][ ][ ][ ][ ][ ][ ]

1. Identification Number 2. Alphacode 3. Date of review: mm/dd/yyyy

Exposures

4. a. Exposed to industrial solvents ..... IND_SOLV
   0=No, 1=Yes, past, 2=Yes, current, 3=Both current and past, 4=9/11 Responder, 9=Unknown
   b. Number of years exposed to solvent ..... IND_SOLV_YRS

5. a. Exposed to asbestos? ..... ASBESTOS
   0=No, 1=Yes, past, 2=Yes, current, 3=Both current and past, 4=9/11 Responder, 9=Unknown
   b. Number of years exposed to asbestos ..... ASBESTOS_YRS

6. a. Exposed to mineral dust? ..... MINERAL_DUST
   0=No, 1=Yes, past, 2=Yes, current, 3=Both current and past, 4=9/11 Responder, 9=Unknown
   b. Number of years exposed to mineral dust ..... MINERAL_DUST_YRS

7. a. High altitude exposure? (≥5, 000 ft) ..... ALTITUDE
   0=No, 1=Yes, past, 2=Yes, current, 3=Both current and past
   b. Number of years of high altitude exposure ..... ALTITUDE_YRS

8. a. Exposure to animals and birds? (0=No, 1=Yes) ..... ANIMALS
   0=No, 1=Yes, primarily inside home, 2= Yes, primarily outside
   b. Dog(s) ..... DOGS
   c. Cat(s) ..... CATS
   d. Bird(s) ..... BIRDS
   e. Horse(s) ..... HORSES

9. Exposure to molds? (0=No, 1=Yes, 4=9/11 Responder, 9=Unknown) ..... MOLDS

Drug Use

10. a. Use of diet drugs? ..... DIET_USE
    (0=No history, 1=Yes, in the past 3 years, 2=Yes, but more than 3 years ago, 9=Unknown or refused)
    b. Was diet drug(s) prescribed by physician? (0=No, 1=Yes) ..... DIET_PRESC
    c. Was diet drug(s) purchased over-the-counter? (0=No, 1=Yes) ..... DIET_OTC
    Specify name(s) of diet drug(s): _____ DIET_DRUGS

11. Recreational drug use? ..... REC_USE
    0=No history, 1=Yes, in the past 3 years, 2=Yes, but more than 3 years ago, 9=Unknown or refused

    For items 11a-f answer 0=No, 1=Yes, 9=Unknown or refused
    a. Marijuana ..... MARIJUANA
    b. Cocaine ..... COCAINE

For items 11a-f answer 0=No, 1=Yes, 9=Unknown or refused, continued:

c. Amphetamine derivative ..... AMPHETAMINE
d. Narcotics ..... NARCOTICS
e. Opiates ..... OPIATES
f. Other recreational drugs ..... OTHER_REC

Smoking

12. a. Do you or did you smoke cigarettes? ..... CIGARETTES
(0=No, never smoked-skip to Item 13, 1=Yes, former smoker, 2=Yes, current smoker, 9=Unknown or refused)

b. How old were you when you began to smoke cigarettes regularly? ..... CIG_AGE_START

c. In an average day, how many cigarettes do/did you usually smoke? ..... CIG_DAY_CT
(20 if one pack, 40 if two packs, etc.)

d. At approximately what age did you quit smoking cigarettes? (leave this blank if still smoking cigarettes) ..... CIG_AGE_QUIT

13. a. Do you or did you smoke e-cigarettes? ..... E_CIG
(0=No, never smoked-skip to Item 14, 1=Yes, former smoker, 2=Yes, current smoker, 9=Unknown or refused)

b. How old were you when you began to smoke e-cigarettes regularly? ..... E_CIG_START

c. At approximately what age did you quit smoking e-cigarettes? (leave this blank if you are still smoking) ..... E_CIG_QUIT

14. a. Do you or did you ever smoke cigars? ..... CIGARS
(0=No, 1=Yes, former smoker, 2=Yes, current smoker, 9=Unknown or refused)

b. Do you or did you ever smoke a tobacco pipe? ..... PIPE
(0=No, 1=Yes, former smoker, 2=Yes, current smoker, 9=Unknown or refused)

c. Have you or did you ever use smokeless tobacco? ..... SMOKELESS
(0=No, 1=Yes, former user of smokeless tobacco, 2=Yes, current user of smokeless tobacco, 9=Unknown or refused)

Alcohol:

15. a. Do you or did you drink alcohol? ..... ALC
(0=No, never drank alcohol, skip to Item 200, 1=Yes, in the past, 2=Yes, current drinker, 9=Unknown or refused)

b. Usual number of drinks of wine, beer or liquor during an average week? ..... ALC_WK_CT
(a drink is 4 oz. of wine, a can of beer, or 1-1/2 oz. of hard liquor, including non-bonded liquor/moonshine)

200. Date form completed (mm/dd/yyyy) ..... __/__/COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __/__/ENTER_DT
Username of person entering this form ENTER_USER

08/23/2018: Q4, 5, 6, 9 added response code 9=Unknown

PVD_THROMBOPHILIA

PVDOMICS

PVDOMICS STUDY
Thrombophilia History - Form #106

Instructions: This form is used to capture participant's history thrombophilia history and family history if indicated. One form should be completed for each participant. Information should be obtained from medical records, local physician records, and participant interview. It should include any current diagnoses and past pertinent history.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date of review: mm/dd/yyyy

Provide a response for both personal history and for biological relative(s) who may have a history of the following conditions.

Code the following: 0=No, 1=Yes, confirmed, 2=Yes, suspected, 8=N/A, adopted, 9=Unknown
For Q4-5: Participant Provoked/Unprovoked column, use 1=Provoked, 0=Unprovoked

	Participant History?	Participant Age (*in yrs*) of First Event?	Participant Provoked*/ Unprovoked	Family History (*if known*)
4. Deep vein thrombosis (DVT)?	DVT	DVT_AGE	DVT_PROVOKE	DVT_FAMILY
5. Pulmonary embolism (PE)?	PE	PE_AGE	PE_PROVOKE	PE_FAMILY
6. Myocardial infarction (MI)?	MI	M		MI_FAMILY
7. Cerebrovascular accident (CVA)?	CVA			CVA_FAMILY
8. Arterial thrombosis in other site?	ART_THR			ART_THR_FAMILY

9. Were any of the above events while on anticoagulation therapy? (0=No, 1=Yes, 9=Unknown) ANTICOAG_THERAPY

***For Questions 4 and 5 only: Definitions**

PROVOKED

a) Within the 3 months prior to VTE has patient had surgery, trauma, immobilization for > 3 days, hospitalization for > 3 days for an acute medical illness, presence of central venous catheter OR

b) Concurrent to VTE has the patient used oral contraceptives or hormone replacement Rx, is pregnant, OR

c) Had episode of prolonged travel (>4 hrs) within the past 4 weeks

UNPROVOKED - None of the above

Continued on next page

Code the following: 0=No, 1=Yes, confirmed, 2=Yes, suspected, 8=N/A, adopted, 9=Unknown

	Participant History?	Family History (*if known*)
10. Clotting disorder?	CLOTTING	CLOTTING_FAMILY
11. Platelet abnormality?	PLT_ABN	PLT_ABN_FAMILY
a. Thrombocytosis	THROMBOCYTOSIS	THROMBOCYTOSIS_FAMILY
b. Thrombocytopenia	THROMBOCYTOPENIA	THROMBOCYTOPENIA_FAMILY
c. Other	PLT_ABN_OTHER	PLT_ABN_OTHER_FAMILY
12. Chronic hemolytic anemia?	HEMO_ANEMIA	
a. Sickle cell?	SICKLE_CELL	
b. Thalassemia?	THALASSEMIA	
c. Other?	HEMO_ANEMIA_OTHER	
13. Myelodysplastic syndrome?	MYELODYSPLASTIC_SYND	
14. Lymphoma	LYMPHOMA	
15. Leukemia	LEUKEMIA	

16. Has the participant a prior history of antiplatelet or anticoagulant therapy? ANTIPLT_ANTICOAG_THERAPY
(0=No, 1=Yes, current*, 2=Yes, history only, 3=Both current and previous history) *(see appendix for medication examples)*
Note: Report current anticoagulation therapy use on Form 110.

17. Does or did the participant have an intravenous indwelling catheter? CATHETER
0=No 2=Yes, history only
1=Yes, current 3=Yes, both current and previous history

18. Was an indwelling catheter associated with a DVT or PE? (0=No, 1=Yes, 9=Unknown) CATH_DVT_PE

200. Date form completed (mm/dd/yyyy) ___/___/COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ENTER_DT

Username of person entering this form ENTER_USER

PVD_FAM_HIST

PVDOMICS

PVDOMICS STUDY
Review of Family History of Pulmonary Hypertension
Form #107

Instructions: This form is completed once per participant.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date of family history review (mm/dd/yyyy)

4. Mother's race? ..... MOM_RACE

1=American Indian/Alaska Native
2=Asian
3=Native Hawaiian or Other Pacific Islander
4=Black or African American
5=White
6=More than one race
9=Unknown or not reported

a. Hispanic or Latino ethnicity? (0=No, 1=Yes, 9=Unknown or not reported) ..... MOM_HISPANIC

5. Father's race? ..... DAD_RACE

1=American Indian/Alaska Native
2=Asian
3=Native Hawaiian or Other Pacific Islander
4=Black or African American
5=White
6=More than one race
9=Unknown or not reported

a. Hispanic or Latino ethnicity? (0=No, 1=Yes, 9=Unknown or not reported) ..... DAD_HISPANIC

6. Family history of pulmonary hypertension? (0=No, 1=Yes, 8=Adopted, unknown, 9=Unknown) PH_HISTORY

a. Living family member enrolled in PVDOMICS? (0=No, 1= Yes, 9=Unknown) PVD_ENROLLED

For biological relative(s) with history of pulmonary hypertension, code the following:
0=No, 1=Yes, confirmed, 2=Yes, suspected, 8=N/A, No such relative, 9=Unknown

	Have PH?	WHO Group Class? (if known)	Unexplained Sudden Death?	Age (years) at death?
7. Mother	MOM_PH	MOM_WHO_GRP	MOM_DEATH	MOM_DEATH_AGE
8. Father	DAD_PH	DAD_WHO_GRP	DAD_DEATH	DAD_DEATH_AGE
9. Sister(s)	SIS_PH	SIS_WHO_GRP	SIS_DEATH	SIS_DEATH_AGE
a. Niece(s)	MAT_NIECE_PH	MAT_NIECE_WHO_GRP	MAT_NIECE_DEATH	MAT_NIECE_DEATH_AGE
b. Nephew(s)	MAT_NEPHEW_PH	MAT_NEPHEW_WHO_GRP	MAT_NEPHEW_DEATH	MAT_NEPHEW_DEATH_AGE
10. Brother(s)	BRO_PH	BRO_WHO_GRP	BRO_DEATH	BRO_DEATH_AGE
a. Niece(s)	PAT_NIECE_PH	PAT_NIECE_WHO_GRP	PAT_NIECE_DEATH	PAT_NIECE_DEATH_AGE
b. Nephew(s)	PAT_NEPHEW_PH	PAT_NEPHEW_WHO_GRP	PAT_NEPHEW_DEATH	PAT_NEPHEW_DEATH_AGE

	Have PH?	WHO Group Class? (if known)	Unexplained Sudden Death?	Age (years) at death?
11. Maternal grandmother	MAT_GRANDMA_PH	MAT_GRANDMA_WHO_GRP	MAT_GRANDMA_DEATH	MAT_GRANDMA_DEATH_AGE
12. Maternal grandfather	MAT_GRANDPA_PH	MAT_GRANDPA_WHO_GRP	MAT_GRANDPA_DEATH	MAT_GRANDPA_DEATH_AGE
13. Paternal grandmother	PAT_GRANDMA_PH	PAT_GRANDMA_WHO_GRP	PAT_GRANDMA_DEATH	PAT_GRANDMA_DEATH_AGE
14. Paternal grandfather	PAT_GRANDPA_PH	PAT_GRANDPA_WHO_GRP	PAT_GRANDPA_DEATH	PAT_GRANDPA_DEATH_AGE
15. Maternal Aunt	MAT_AUNT_PH	MAT_AUNT_WHO_GRP	MAT_AUNT_DEATH	MAT_AUNT_DEATH_AGE
16. Maternal Uncle	MAT_UNCLE_PH	MAT_UNCLE_WHO_GRP	MAT_UNCLE_DEATH	MAT_UNCLE_DEATH_AGE
17. Paternal Aunt	PAT_AUNT_PH	PAT_AUNT_WHO_GRP	PAT_AUNT_DEATH	PAT_AUNT_DEATH_AGE
18. Paternal Uncle	PAT_UNCLE_PH	PAT_UNCLE_WHO_GRP	PAT_UNCLE_DEATH	PAT_UNCLE_DEATH_AGE
19. Child 1	CHILD1_PH	CHILD1_WHO_GRP	CHILD1_DEATH	CHILD1_DEATH_AGE

Note: If Q19=8 (no children), skip to Q200

20. Child 2	CHILD2_PH	CHILD2_WHO_GRP	CHILD2_DEATH	CHILD2_DEATH_AGE
21. Child 3	CHILD3_PH	CHILD3_WHO_GRP	CHILD3_DEATH	CHILD3_DEATH_AGE
22. Child 4	CHILD4_PH	CHILD4_WHO_GRP	CHILD4_DEATH	CHILD4_DEATH_AGE
23. Child 5	CHILD5_PH	CHILD5_WHO_GRP	CHILD5_DEATH	CHILD5_DEATH_AGE
24. Child 6	CHILD6_PH	CHILD6_WHO_GRP	CHILD6_DEATH	CHILD6_DEATH_AGE
25. Child 7	CHILD7_PH	CHILD7_WHO_GRP	CHILD7_DEATH	CHILD7_DEATH_AGE
26. Child 8	CHILD8_PH	CHILD8_WHO_GRP	CHILD8_DEATH	CHILD8_DEATH_AGE
27. Child 9	CHILD9_PH	CHILD9_WHO_GRP	CHILD9_DEATH	CHILD9_DEATH_AGE
28. Child 10	CHILD10_PH	CHILD10_WHO_GRP	CHILD10_DEATH	CHILD10_DEATH_AGE

200. Date form completed (mm/dd/yyyy) ..... ___/COMP_DT___

201. Username of person completing/reviewing completeness of this form: ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ENTER_DT

Username of person entering this form: ___ ENTER_USER

PVD_MEDS , PVD_MEDS_IMMUNO_CHEMO_DTL
PVD_MEDS_MEDS_SUPPS_DTL, PV...

Revision of 06/23/2017

PVDOMICS

PVDOMICS STUDY

PH and Concomitant Medications Form #110

Instructions: This form is completed once per participant. This form should record all medications including those medications prescribed by physician, nurse practitioner, or physician assistant as well as any over-the-counter medications such as multivitamins, nutraceuticals, herbal remedies and so on. Review participant's medical record and **ask the participant** what medications that are prescribed and/or OTC meds usually taken even if not taken that day but would take normally.

Note: A Form 110 list of medications that includes but is not limited to, a variety of medications and is provided as a supplement document-see Forms webpage.

PID | AC | VISIT_DT

1. Identification Number
2. Alphacode
3. Date of medication review (mm/dd/yyyy)

4. In the last three months has participant received any of following therapies?
   a. Blood transfusion(s) (0=No; 1=Yes)..... TRANSFUSION
   b. Platelet transfusion(s) (0=No; 1=Yes) ..... PLATELETS
   c. Intravenous immunoglobin (IVIG) (0=No; 1=Yes)..... IVIG
   d. Chemotherapy and/or immunosuppressive medications (0=No; 1=Yes, complete table below) ..... IMMUNO_CHEMO

You will be able to enter as many medications as needed.

TABLE: PVD_MEDS_IMMUNO_CHEMO_DTL

Name of Immunosuppression/Chemotherapy Medications	Duration 1=0-3mos, 2=4-6 mos, 3=7-12mos, 4= >1 year	Last Dose 1=0-3mos, 2=4-6 mos, 3=7-12mos, 4= >1 year
MED	DURATION	LAST_DOSE

PID, AC, CODE,

5. Is the participant currently taking any medications and/or OTC supplements? (0=No, 1=Yes)..... ___

You will be able to enter as many medications as needed.

TABLE: PVD_MEDS_MEDS_SUPPS_DTL

Name of Medication/Supplement
MED

Name of Medication/Supplement

PID, AC, CODE,

Name of Medication/Supplement

Name of Medication/Supplement

6. Is the participant currently using oxygen at **rest**? (0=No; 1=Yes) ..... REST_O2 ___

   a. If yes, how much does participant report using in liters per minutes (lpm) ..... REST_LPM

   1=1-2 lpm 3=5-6 lpm 5=greater than 8 lpm
   2=2-4 lpm 4=6-8 lpm

7. Is the participant currently using oxygen at **night**? (0=No; 1=Yes)..... NIGHT_O2 ___

   a. If yes, how much does participant report using in liters per minutes (lpm) NIGHT_LPM ___

   1=1-2 lpm 3=5-6 lpm 5=greater than 8 lpm
   2=2-4 lpm 4=6-8 lpm

8. Is the participant currently using oxygen on **exertion**? (0=No; 1=Yes) ..... EXERTION_O2 ___

   a. If yes, how much does participant report using in liters per minutes (lpm) EXERTION_LPM

   1=1-2 lpm 3=5-6 lpm 5=greater than 8 lpm
   2=2-4 lpm 4=6-8 lpm

200. Date this form completed (mm/dd/yyyy) ..... ___ ___/ ___ ___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMPUSER ___

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___ ___/ ___ ___/ ENTER_DT

Username of person entering this form ___ ___/ ENTER_USER

PVDOMICS

PVDOMICS STUDY
Functional Class Form #115

Instructions: This form is to be completed by the Clinical Center PI (or other physician investigator) to document the participant's Functional Class (FC) at time of PVDOMICS assessment (visits). Controls will not have FC assessed.

If not previously classified, WHO is the Functional Class to be used as per agreement on the 03/01/2019 Steering Committee conference call.

Note: A Functional Class (FC) assessment done within +/- 6 weeks around enrollment date is acceptable.

1. Identification Number **PID** 2. Alphacode **AC** 3. Date of FC review/assessment (mm/dd/yyyy) **VISIT_DT**

4. Was a Functional Class (FC) determined at the time of enrollment? **DETERMINED** ____
   1= Yes, WHO FC from the time of enrollment is available (skip to Q5)
   2= Yes, NYHA FC from time of enrollment is available (skip to 6)
   3= Yes, but unknown which criteria was used (skip to Q7)
   4= No, but the PI can determine FC retrospectively using WHO criteria (skip to Q5)
   5= No, after careful review, there is not enough data available. PI cannot determine the FC retrospectively (skip to 'Rationale for Adjudication Committee')

5. a. What was/is the WHO Functional Class? **FUNCTIONAL_CLASS** ____
   1=Class 1, 2=Class 2, 3=Class 3, 4=Class 4

   b. How was/is WHO Functional Class assessed? **ASSESSED** ____
   1= Documented in participant's medical records at time of visit for parent PVDOMICS study
   2= Documented in participant's medical records within 6 weeks PRIOR to enrolling in (parent) PVDOMICS study
   3= Not documented in past records but PVDOMICS Study PI reviewed previous records and determined the Functional Class. This case will be reviewed by the Adjudication Committee.

6. a. What was the NYHA Functional Class? **NYHA_FUNCT_CLASS** ____
   1=Class 1, 2=Class 2, 3=Class 3, 4=Class 4

   Note: If classification is a '3B', it should be assigned to Class 3 per Steering Committee.

   b. How was NYHA Functional Class assessed? **NYHA_ASSESSED** ____
   1=Documented in participant's medical records at time of visit for PVDOMICS study.
   2=Documented in participant's medical records within 6 weeks PRIOR to enrolling in PVDOMICS study.
   3=Not documented in past records but PVDOMICS Study PI reviewed previous records and determined the Functional Class. This case will be reviewed by the Adjudication Committee.

7. a. *For unknown type of FC used:* What was/is the Functional Class? **UNK_FUNCT_CLASS** ____
   1=Class 1, 2=Class 2, 3=Class 3, 4=Class 4

   b. How was (unknown classification) type Functional Class assessed? **UNK_ASSESSED** ____
   1=Documented in participant's medical records at time of visit for PVDOMICS study.
   2=Documented in participant's medical records within 6 weeks PRIOR to enrolling in PVDOMICS study.

Rationale for Adjudication Committee
RATIONALE

199. Name of physician who completed assessment:.....**PHYS_USERNAME** ___ ___ ___ ___ ___ ___ ___
(*Username of physician is the first 6 letters of last name and first initial.)*

200. Date this form completed (mm/dd/yyyy).....**COMP_DT** ___ ___/___ ___ /___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form.....**COMP_USER** ___ ___ ___ ___ ___ ___ ___

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __ **ENTER_DT**

Username of person entering this form__ __ __ __ __ __ __ **ENTER_USER**

WHO Functional Classification

WHO Class	Description
Class I	Pulmonary hypertension without resulting limitation of physical activity; Ordinary physical activity does not cause undue dyspnea or fatigue, or chest pain or near-syncope;
Class II	Pulmonary hypertension resulting in a slight limitation of physical activity; Comfortable at rest; Ordinary physical activity causes undue dyspnea or fatigue, or chest pain or near-syncope;
Class III	Pulmonary hypertension resulting in a marked limitation of physical activity; Comfortable at rest; Less than ordinary physical activity causes undue dyspnea or fatigue, or chest pain or near-syncope;
Class IV	Pulmonary hypertension resulting in inability to carry out any physical activity without symptoms; Signs of right heart failure; Marked limitation of physical activity; Dyspnea and/or fatigue may be present at rest; Discomfort is increased by any physical activity;

Revision of 06/23/2017

PVD_VITALS

PVDOMICS

PVDOMICS STUDY
Study Visit Vital Signs - Form #120

Instructions: This form is completed at the beginning of every PVDOMICS study visit to collect vital signs.

PID | | | | | | | AC | | VISIT_DT | | | | | | | |

1. Identification Number 2. Alphacode 3. Date of study visit: mm/dd/yyyy

4. Reason for this visit ..... REASON
   1=Initial visit for PVDOMICS Study
   2=Complete PVDOMICS Study tests

5. Did participant refrain from caffeine, smoking and exercise at least 30 minutes prior to measurements? (0=No, 1=Yes) ..... REFRAIN
   If no, then wait 30 minutes before taking vitals.

PULSE AND BP MEASUREMENTS-TAKEN ON BARE, UPPER ARM ONLY

Using a timer, wait 15 minutes while the patient is sitting quietly in a chair without talking, eating or drinking. The participant should be sitting upright with their back supported and their feet flat on the floor. If their feet do not touch the floor, then their feet should hang without crossing or moving.

6. Pulse (beats per minute) ..... PULSE ___ ___ ___
7. Respiratory rate (breaths per minute)(at rest) ..... RESP ___ ___
8. Resting blood pressure (systolic/diastolic) (mmHg) ..... SYS ___ / DIA ___
9. Temperature taken sublingually (°F) ..... TEMP ___ ___ . ___

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

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT ___ ___ / ___ ___ / ___ ___ ___ ___

Username of person entering this form ENTER_USER ___ ___ ___ ___ ___ ___ ___ ___

PVD_REPROD_HX

PVDOMICS

PVDOMICS STUDY
Female Reproductive History Form #121

Instructions: This form is completed once for each female enrolled in the study and should be completed at the first PVDOMICS visit.

PID | | | | | | |
1. Identification Number

AC | |
2. Alphacode

VISIT_DT | | | | | | | |
3. Date of female hx review: mm/dd/yyyy

Female Reproductive History

4. Age at first menses ..... MENSES_AGE
(Enter 99 for unknown or refused)

5. Menstrual cycle status ..... MENSES_STATUS
1=Currently menstruating (≤ 3 months)
2=Last menstrual cycle > 3 months - ≤1 year ago
3=Last menstrual cycle >1 year - ≤ 5 years ago
4=Last menstrual cycle > 5 years ago

6. a. Are or were your periods regular? (0=No, 1=Yes, 9=Unknown) ..... REGULAR ___

b. If your periods are or were irregular, approx. how many times per year do you or did you have your periods? ..... NO_TIME_YR

7. a. Current child-bearing potential ..... CHILD_BEARING
1=Non-surgically sterilized and not post-menopausal: "woman of childbearing potential"
2=Surgically sterilized (includes endometrial ablation)
3=Post-menopausal (one year since last period)

b. If item 7a=1 (woman of childbearing potential), does the participant agree to use birth control? (0=No, 1=Yes) ..... BIRTH_CONTROL

8. Any gynecological surgery? (0=No, 1=Yes, answer Q8a-e) ..... GYN_SURGERY
For the following questions respond (0=No, 1=Yes)

a. Total abdominal hysterectomy (TAH)? ..... TAH ___

b. Oophorectomy? ..... OOPHOR ___

c. Endometrial ablation? ..... ABLATION ___

d. Tubal ligation? ..... TUBAL_LIGATION

e. Other gynecological surgery ..... OTH_SURG ___:

(specify - *not entered into database*): _____)

9. Ever been pregnant? (0=No, 1=Yes, answer Q9a-b, 9=Unknown or refused) ..... PREGNANT ___

a. Number of pregnancies ..... NO_PREGS ___

b. Number of live births ..... NO_LIVE_BIRTHS

10. Ever used contraceptives? (0=No *(includes abstinence)*, 1=Yes, answer Q10a-i) ..... CONTRACEPTIVES

For Q10a-i: (0=No, 1=Yes, current use, 2=Past use, 3=Both current and past use [*started, stopped and restarted*] 9=Unknown.)

For number of years of use, ask for participant's best guess.

a. Oral (estrogen/progesterone) contraceptive(s) use? ..... ORAL_ESTRO

1. Overall, number of years taking oral contraceptive(s) ..... ORAL_ESTRO_YRS

b. Oral progestogens (progestins) only (POP's) contraceptive(s) use? *(see attached list of names)* ORAL_PROG
For response to Q10b: use above codes if known progestin use. If form completed prior to 10/10/2017only, can use 9=Unknown.

1. Overall, number of years taking oral progestogen contraceptive(s) ..... ORAL_PROG_YRS

c. Patch for contraception? ..... PATCH

1. Overall, number of years using patch. ..... PATCH_YEARS

d. Levonorgestrel-releasing implant (e.g. Jadelle, Norplant)? ..... LEVONOR

1. Overall, number of years using implant ..... LEVONOR_YRS

e. Implant for contraception (not otherwise specified)? ..... OTH_IMPLANT

1. Overall, number of years having implant ..... OTH_IMPLANT_YRS

f. IUD with hormone(s)? ..... IUD_W_HORM

1. Overall, number of years using IUD with hormone ..... IUD_W_HORM_YRS

g. IUD without hormone(s)? ..... IUD_WO_HORM

1. Overall, number of years using IUD without hormone ..... IUD_WO_HORM_YRS

h. Vaginal ring? ..... VAGINAL_RING

1. Overall, number of years using a vaginal ring ..... VAGINAL_RING_YRS

i. Depo-Provera? ..... DEPO

1. Overall, number of years using Depo-Provera ..... DEPO_YEARS

11. Ever used hormone replacement therapy (HRT)? ..... HRT

1. Overall, number of years receiving HRT ..... HRT_YEARS

200. Date this form completed (mm/dd/yyyy) ..... ___ ___/___ ___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... ___ ___ ___ COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___ ___/___ ___/ ENTER_DT

Username of person entering this form ___ ___ ___ ENTER_USER

PROGESTOGEN-ONLY PILLS (POPS) [colloquially known as **mini pills**]
Barr
Camila®
Cerazette
Crinone
desogestrel
EC-RX Progesterone
Endometrin
Errin®
etynodiol diacetate
Femulen
First-Progesterone VGS 100;
First-Progesterone VGS 200;
First-Progesterone VGS 25 [DSC]
First-Progesterone VGS 400 [DSC]
First-Progesterone VGS 50 [DSC]
Gedeon
Heather®
Jolivette®
Lactinette
levonorgestrel
Losestrin
lynestrenol
Microlut
Micronor®
minipill
Nora-BE
Norethidrone®
norethindrone
norethisterone (norethindrone)
Norgeston
norgestrel
Noriday
Norkolut
Nor-Q.D.®
Organon
Ovrette®¶
POP
Primolut-Nor
Prometrium

PVD_WAIST_HIP

Revision 07/20/2017

PVDOMICS

PVDOMICS STUDY
Waist/Hip Ratio Measures - Form #131

Instructions: Review PVDOMICS MOP Chapter 36 on how to measure waist/hip circumference.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date of W/H measures: (mm/dd/yyyy)

Waist/Hip Circumference Measurements - This set of measurements is completed once per participant.

4. Were waist and hip measurements completed? ..... COMPLETED ___

1=Yes, test was completed for PVDOMICS Study (answer Q5-7)
2=No, wheelchair use only.
3=No, logistics problem related to the participant
4=No, medical contraindication/safety issue detected
5=No, logistic problem related to the PVDOMICs clinical site (e.g., staffing, scheduling)
6=No, participant refused

5. Waist measurement at approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest (cm) ..... WAIST_CM ___ ___ ___.___

6. Hip circumference around the widest portion of the buttocks (cm) ..... HIP_CM ___ ___ ___.___

Calculated waist/hip ratio ..... WH_RATIO ___.___

(Database will calculate waist/hip ratio automatically. Write the value in the greyed out box on this paper form.)

7. Username of person taking waist/hip measurements ..... CERT_USER _____

(Person must be trained to take waist/hip measurements and date trained be entered on Form 10-Study Personnel in the PVDOMICs database in order for name to appear in the drop down box).

200. Date this form completed (mm/dd/yyyy) ..... COMP_DT ___/___/_____

201. Username of person reviewing completeness of this form ..... COMP_USER _____

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT

Username of person entering this form ENTER_USER

CC-N

Clinical Center #

PVD_BIA

PVDOMICS

PVDOMICS STUDY
Height, Weight and Bioelectric Impedance Assessment (BIA) - Form #132

Instructions:
This form serves two purposes: 1) records measured height/weight used in analyses (*see Section 1*) and, 2) captures whether or not the BIA test was completed and the results were recorded from the machine (*see Section 2*).

The Bioelectric Impedance Assessment (BIA) is a standing measurement device that measures body composition. PVDOMICS Study is using the Tanita SC-240 device. Review the detailed MOP Chapter 37 for specific instructions on how to complete the testing procedure.

You will need to ask the participant whether he/she has an implanted defibrillator or pacemaker or other mechanical implants of any kind , and if he or she does, do not do the BIA test.

Do not do the test if the patient is a bilateral amputee.

Set the device to Standard or Athletic mode depending on overall body habitus. Have participant remove bulky clothes, cell phones, pagers to avoid variability in accuracy of weight. For clothes weight, input 1 kg as uniform estimate.

Note: Ideally, this test should be rescheduled for any of the following conditions, please refer back to MOP Chapter 37 for more information:

- Participant has exercised or taken a sauna within 12 hours
- Participant walked or eaten a large meal within 3 hours of the test
- Female participant is menstruating.

PID [| | | | | |] 1. Participant ID #

[AC] 2. Alpha Code

[| | | | | | | |] VISITDT 3. Date of Ht/Wt/BIA Measurement: mm/dd/yyyy

Section 1: Height and Weight

4. Were height and weight measurements taken? (0=No, 1=Yes, complete 4a-b) ..... HT_WT __
   a. Standing measured height (cm) ..... HT __.__
   b. Current measured weight (kg) ..... WT __.__
   (after removing bulky clothing and other items such as coins, phones, etc.)
5. Does participant have any amputated limbs? (0=No, 1=Yes, complete 5a-b) ..... AMP __
   a. Left (0=none, 1=below knee or elbow, 2=above knee or elbow) ..... AMP_LEFT
   b. Right (0=none, 1=below knee or elbow, 2=above knee or elbow) ..... AMP_RIGHT

Section 2: BIA Testing

6. Was a barefoot standing BIA measurement performed? ..... BIA_PERFORM
   1=Yes, test was completed for PVDOMICS Study (answer Q8-13)
   2=No, wheelchair use only.
   3=No, logistics problem related to the participant
   4=No, medical contraindication/safety issue detected
   5=No, logistic problem related to the PVDOMICs clinical site (e.g., staffing, scheduling)
   6=No, participant refused

7. Time of test (24 hr clock) ..... TEST_TM : _ _
8. Device mode (1=Standard, 2=Athletic-*see Tanita SC-240 device manual*) ..... DEVICE_MODE
9. Measured body fat (%) ..... BODY_FAT _ _ . _
10. Measured BMI ..... BMI _ _ _ . _
11. Total body water (%) ..... BODY_WATER _ _
12. Impedance (50 kHz) ..... IMPEDANCE _ _

200. Date this form completed (mm/dd/yyyy) ..... _ _/_ _/ COMP_DT
201. Username of study certified person who performed this test ..... _ _ _ COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT

Username of person entering this form _ _ _ ENTER_USER

PVD_WALK_TEST

PVDOMICS

PVDOMICS STUDY
Six-Minute Walk Test Form #133

Instructions: Review PVDOMICS MOP Chapter prior to completing participant's 6-minute walk test (6MWT). Borg Dyspnea Scale is appended to end of this form for quick reference.

PID [| | | | | |] 1. Identification Number

AC [| |] 2. Alphacode

[| | | | | | | |] 3. Date of 6-minute walk test (mm/dd/yyyy) VISIT_DT

4. a. Is participant capable of completing a 6-minute walk test? ..... CAPABLE
   0=No, wheelchair use only, skip to Q200
   1=No, medical condition significantly restricts walking abilities, skip to Q200
   2=Yes, no walking restrictions
   3=Yes, but will need to use a mobility device such as cane, crutches
   4=No, PI feels that performing 6MWT would jeopardize participant's safety and test should not be started, skip to Q200

   b. If 4a=3, type of walking aid used? ..... AID_USED
   1=Cane/arm-assist cane
   2=Crutches
   3=Walker
   4=Rollator (rolling walker)
   8=Other, specify: _____ AID_USED_OTH

5. Does this participant have a congenital heart condition? (0=No, 1=Yes) ..... HEART_COND

6. a. Start time of 10-minute rest period (24-hour clock) (hh:mm) ..... REST_START_TM

   b. Has participant refrained from doing any rigorous activity in the last 2 hours? (0=No, 1=Yes) ..... RIGOROUS_ACTIVITY

6-MINUTE WALK TEST - Pre-Test

7. Pre-test blood pressure (systolic/diastolic)(mmHg) ..... PRE_SYS/PRE_DIA

8. Pre-test Borg Dyspnea Score *(use scale on at end of this form)* ..... PRE_AD_SCORE

9. a. Was the provided Masimo oximeter used? (0=No, 1=Yes) ..... MASIMO_USED

   a.1. If Q9a=no, why was Masimo oximeter not used? ..... MASIMO_NOT_USED
   1=Participant tested in location separate from where equipment stored
   2=Equipment malfunctioned (includes new batteries not available.)
   3=Different staff member conducted 6MWT and did not realize that the Masimo equipment should have been used

   b. Was the provided lanyard used? (0=No, 1=Yes) ..... LANYARD_USED

   b.1. If Q9b=no, why was lanyard not used? ..... LANYARD_NOT_USED
   1=Participant refused to wear lanyard
   2=Morbidly obese and lanyard could not be adjusted to fit
   3=Study staff refused to use the lanyard

   c. Type of pulse oximetry probe used? (1=Finger, 2=*Ear-**not recommended***, 3=**Forehead-***preferred*) ..... PROBE_USED

10. Room air oxygen saturation at rest (%) ..... OXY_SAT
    (Room air oxygen after 5 minutes of resting. If on 4L of supplemental oxygen at rest, must get permission from supervising provider.)

11. Is supplemental O2 required to obtain a SpO2 at rest ≥ 92%? (0=No-skip to Q12, 1=Yes) ..... SUPP_O2
    a. Mode of oxygen administration? (1=Nasal cannula, 2=Rebreather, 8=Other) ..... MODE_ADMIN
    b. Type of delivery? (1=Continuous, 2=Pulse) ..... DELIVERY_TYPE
    c. What is O_2 flow used during 6MWT (L/M)? ..... O2_FLOW
    d. How did participant transport oxygen during 6MWT? (1=Pull, 2=Push, 3=Carry, protocol deviation) ..... O2_TRANSPORT
12. Pre-test baseline SpO_2 (%) (resting/sitting, on O_2) ..... PRE_SPO2
    (Note: If participant requires oxygen, starting SpO2 (on oxygen) will be different than room air O2 saturation at rest. If the test is done on room air, then this value will be the same as Q10. Continuous pulse oximetry must be measured throughout the test. Technician should NOT walk with the participant)
13. Pre-test baseline heart rate (beats/minute) (resting/sitting) ..... PRE_HT_RATE

Post-Test

14. a. Total distance walked (meters) ..... TOTAL_DIS_WALK
    b. Time participant started to walk (24-hour clock) (hh:mm) ..... __ __:__ __
    c. Time participant stopped walking (24-hour clock) (hh:mm) ..... STOP_TM
15. a. SpO_2 at end of walk (%) ..... SPO2_END_WALK
    b. SpO2 at 1 minute recovery (%) ..... SPO2_1_MIN_RECOV
    c. SpO2 at 2 minutes recovery (%) ..... SPO2_2_MN_RECOV
    d. Lowest SpO2 recorded (%) ..... LOWEST_SPO2
    e. Time of lowest recorded SpO2 (24-hour clock) (hh:mm) ..... LOWEST_SPO2_TM
16. a. Heart rate at end of walk (beats/minute) ..... HT_RATE_END_WALK
    b. Heart rate at 1 minute recovery (beats/minute) ..... HT_RATE_1_MIN_RECOV
    c. Heart rate at 2 minutes recovery (beats/minute) ..... HT_RATE_2_MIN_RECOV
17. Post-test blood pressure (systolic/diastolic)(mmHg) ..... POST_SYS / POST_DIA
18. Post-test Borg Dyspnea Score *(use scale at the end of this form)* ..... POST_BD_SCORE
19. Total number of stops ..... TOTAL_STOP
20. Duration of combined stops (minutes:seconds) DVR_STOP_SEC , ... DVR_STOP_MIN
21. Was walk test terminated before 6 minutes? (0=No, 1=Yes, by study staff, 2=Yes, by participant) ..... TEST_TERMINATED
    If No, skip to Question 199.
22. If yes, time test was terminated (24-hour clock) (hh:mm) ..... TEST_TERMINATED_TM

If test terminated, identify reason(s):

a. Chest pain (0=No, 1=Yes) ..... CHEST_PAIN
b. Dizziness (0=No, 1=Yes) ..... DIZZINESS
c. Dyspnea (0=No, 1=Yes) ..... DYSPNEA
d. Near syncope (lightheaded, feeling faint) (0=No, 1=Yes) ..... SYNCOPE
e. Ataxic gait (staggering) (0=No, 1=Yes) ..... ATAXIC_GAIT
f. Lower extremity claudication (cramping) (0=No, 1=Yes) ..... CLAUDICATION
g. Fatigue, weakness (0=No, 1=Yes) ..... FATIGUE
h. Mental confusion (0=No, 1=Yes) ..... CONFUSION
i. Lower extremity joint/leg pain (0=No, 1=Yes) ..... JOINT_LEG_PAIN
j. Diaphoresis, pale or ashen appearance (0=No, 1=Yes) ..... DIAPHORESIS
k. Participant refused to continue (0=No, 1=Yes) ..... REFUSED
l. Oxygen saturation dropped down to ≤ 80% ..... O2_80PCT
m. Participant fell down ..... FELL_DOWN
n. Other (0=No, 1=Yes) (specify _____) OTHER_SPECIFY

199. Username of PVDOMICs staff member completing this test ..... TEST_USERNAME

200. Date form completed (mm/dd/yyyy) ..... __ __/__ __/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... __ __ COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/ ENTER_DT
Username of person entering this form __ __ __ ENTER_USER

As of 04/16/2018: Q4a: response code of 4 added. Old Q5 'Time of 6MWT' (24-hour clock) (hh:mm) dropped. Q6b. new question 'refrained from rigorous activity added. New Q14b (same as old Q5) & Q14c added. New Q15d added. New Q22 added. Q22, items l & m added. 'Other' is now 22n. 06/15/2018: 9a-b added; Q9c-ear probe not recommended, forehead preferred; Q9a1 & b1 reason why oximeter and/or lanyard not used.

Modified Borg Rating Scale for Perceived Dyspnea

0	Nothing at all
0.5	Very, very slight shortness of breath
1	Very mild shortness of breath
2	Mild shortness of breath
3	Moderate shortness of breath or breathing difficulty
4	Somewhat severe
5	Strong or hard breathing
6	-
7	Severe shortness of breath or very hard breathing
8	-
9	Extremely severe
10	Shortness of breath so severe you need to stop

Reference for Modified Borg Dyspnea Score:
Burdon JGW, Juniper EF, Killian KJ, Hargrave FE, Campbell EJM. The perception of breathlessness in asthma. Am Rev Respir Dis 1982;126:825-8

As of 04/16/2018: Q4a: response code of 4 added. Old Q5 'Time of 6MWT' (24-hour clock) (hh:mm) dropped. Q6b. new question 'refrained from rigorous activity added. New Q14b (same as old Q5) & Q14c added. New Q15d added. New Q22 added. Q22, items l & m added. 'Other' is now 22n. 06/15/2018: 9a-b added; Q9c-ear probe not recommended, forehead preferred; Q9a1 & b1 reason why oximeter and/or lanyard not used.

PVD_SLEEP_INIT

PVDOMICS

PVDOMICS STUDY
Clinical Center Participant Sleep Initialization, Demonstration and Placement - Form #150

Instructions: This form is completed once per participant. Complete this form during initial evaluation of participant and demonstration of sleep monitoring device placement.

Note: Sleep studies using the PVDOMICS protocol can be completed up to 6 months after the end of 6-weeks post-enrollment study protocol period.

PID

1. Identification Number

AC

2. Alpha code

VISIT_DT

3a. Date of initialization, demo and (*if done on the same day*) device placement: (mm/dd/yyyy)

3. b. Was a sleep study machine initialized and sent home with the participant? ..... SLEEP_DONE
   0=No, continue to Q3c.
   1=Yes, continue to Q4.

   c. If not done, what was the reason? ..... SLEEP_ND_REAS
   1=Physician judgment/medical contraindication
   2=Participant not approached to do sleep study (*protocol deviation*)
   3=Logistics issue with clinical center (scheduling conflict, machine not functioning)
   4=Logistics issue with participant
   5=Participant refused

4. Username of PVDOMICS staff member initializing equipment and demonstrating proper device placement to participant ..... INSTRUCTOR
5. Were new AA batteries put in? (0=No, 1=Yes) ..... BATTERIES
6. Are date and time correct on the device? (0=No, 1=Yes) ..... DATE_TIME
7. Sleep device unit identification number ..... S_DEVICE_NO
8. Number of minutes did it take to instruct and demonstrate the sleep monitoring unit: ..... INSTRUCT_MIN
9. What time does participant report going to bed (on average) (24-hour clock) (hh:mm) ..... BED_TM
10. What time does participant report waking up (on average) (24-hour clock) (hh:mm) ..... WAKE_TM
11. Participant baseline SaO2 (%) SAO2
12. Does participant use O_2 during the night? (0=No, 1=Yes) ..... O2_NIGHT
    a. What is usual nighttime O_2 flow (l/min) ..... O2_FLOW
    b. What type of O2 delivery device used (1=Nasal cannula, 2=Mask, 3=Reservoir cannula) ..... O2_DEVICE
    c. Type of O2 delivery (1=Continuous, 2=Pulse) ..... O2_DELIVERY
13. Does participant wear a positive airway pressure (PAP) device at night? (0=No, 1=Yes) ..... PAP_DEVICE
    a. Continuous PAP (CPAP) device? (0=No, 1=Yes) ..... CONT_PAP
       1. Pressure (cmH_2O) ..... CONT_PRESS

b. Bilevel PAP (BiPAP) device? (0=No, 1=Yes) ..... BILEVEL_BIPAP ___

(Q 13b1 removed from form)

2. Back up rate (breaths per minute) ..... BILEVEL_BPM ___
3. IPAP Pressure (cmH_2O) ..... BILEVEL_IPAP_MIN (min) ___ ___ - BILEVEL_IPAP_MAX (max) ___ ___
4. EPAP Pressure (cmH_2O) ..... BILEVEL_EPAP_MIN (min) ___ ___ - BILEVEL_EPAP_MAX (max) ___ ___

c. Auto PAP (APAP) device? (0=No, 1=Yes) ..... AUTO_PAP ___

1. Pressure (cmH_2O) ..... AUTO_PAP_MIN (min) ___ ___ - AUTO_PAP_MAX (max) ___ ___

d. Auto Bilevel PAP (autoBiPAP) device? (0=No, 1=Yes) ..... AUTO_BIPAP ___

(Q 13d1 removed from form)

2. Back up rate (breaths per minute) ..... AUTO_BILEVEL_BPM ___
3. IPAP Pressure (cmH_2O) ..... AUTO_BILEVEL_IPAP_MIN (min) ___ ___ - AUTO_BILEVEL_IPAP_MAX (max) ___ ___
4. EPAP Pressure (cmH_2O) ..... AUTO_BILEVEL_EPAP_MIN (min) ___ ___ - AUTO_BILEVEL_EPAP_MAX (max) ___ ___

e. Adaptive-ServoVentilation device? (0=No, 1=Yes) ..... ADAPT_SERVO ___

(Q 13e1 removed from form)

2. Back up rate (breaths per minute) ..... ADAPT_SERVO_BPM ___
3. IPAP Pressure (cmH_2O) ..... ADAPT_SERVO_IPAP_MIN (min) ___ ___ - ADAPT_SERVO_IPAP_MAX (max) ___ ___
4. EPAP Pressure (cmH_2O) ..... ADAPT_SERVO_EPAP_MIN (min) ___ ___ - ADAPT_SERVO_EPAP_MAX (max) ___ ___
5. Pressure support (PS) ..... ADAPT_SERVO_PS_MIN (min) ___ ___ - ADAPT_SERVO_PS_MAX (max) ___ ___

14. Does participant wear nasal/oral appliance? (0=No, 1=Yes) ..... NASAL_ORAL_APP ___

a. What type of appliance used? ..... APP_TYPE ___

1=Provent
2=Dental appliance
3=Other: specify: _____ APP_TYPE_OTHER

200. Date form completed (mm/dd/yyyy) ..... ___ ___/___ ___/COMP_DT

201. Username of person completing/reviewing completeness of this form..... ___COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) ___ ___/___ ___/ENTER_DT
Username of person entering this form___ ENTER_USER

PVD_SLEEP_QUEST

PVDOMICS

PVDOMICS STUDY
Participant Sleep Study Questionnaire - Form #151

Instructions: Please provide us with information about the night you wore the sleep device. Record your information in the blanks provided below.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Start date when device placed: (mm/dd/yyyy)

4. a. What time did you start putting on the device? DEVICE_HRMI ___ ___ : ___ ___
   hour minutes

   b. Circle one: (1)AM (2)PM DEVICE_AMPM

5. a. What time did you go to bed last night? BED_HRMI ___ ___ : ___ ___
   (time the lights were turned off) hour minutes

   b. Circle one: (1)AM (2)PM BED_AMPM

6. a. What time did you fall asleep last night? ASLEEP_HRMI ___ ___ : ___ ___
   hour minutes

   b. Circle one: (1)AM (2)PM ASLEEP_AMPM

7. a. What time did you get up this morning? UP_HRMI ___ ___ : ___ ___
   hour minutes

   b. Circle one: (1)AM (2)PM UP_AMPM

8. How many times did you wake up last night? WAKEUP_TIMES ___ ___

9. How many times did you get out of bed? OUTBED_TIMES ___ ___
   (for example: to use the bathroom)

10. While you were sleeping:

    a. Did you wear oxygen? OXYGEN Circle one: (0)No (1)Yes

    b. Did you wear PAP sleeping device? PAP_DEVICE Circle one: (0)No (1)Yes

    c. Did you wear other prescribed sleeping device? OTH_DEVICE Circle one: (0)No (1)Yes

    (if yes, what was device: OTH_DEVICE_SPEC)

--Please turn this page over to answer the following questions.--

11. Did any of the following items cause you any discomfort or fall off during the night?

For each question, circle the answer(s) that apply.

a. Belt around your chest? BELT_CHEST (0)No (1)Discomfort (2)Fell Off

b. Belt around your waist? BELT_WAIST (0)No (1)Discomfort (2)Fell Off

c. Tubing in your nose? TUBE_NOSE (0)No (1)Discomfort (2)Fell Off

d. Finger / wrist device? FING_WRST_DEVICE (0)No (1)Discomfort (2)Fell Off

e. Sticky ECG pads? ECG_PADS (0)No (1)Discomfort (2)Fell Off

Please return this completed questionnaire to your PVDOMICS Study Coordinator along with the sleep monitoring device.

Thank you.

This section is completed by the PVDOMICS Study Staff:

200. Date form reviewed (mm/dd/yyyy) COMP_DT _ _ _/_ _ _/_ _ _ _ _

201. Username of person completing/reviewing completeness of this form COMP_USER _ _ _ _

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT _ _ _ _ _ _ _ _ _

Username of person entering this form ENTER_USER

CC_N: Clinical Center #

Revision 11/29/2017

PVD_SLEEP_QUEST

PVDOMICS

PVDOMICS STUDY
Sleep Study Administration Form Questionnaire

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry. Make sure to label this page with identifying patient and visit information.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this sleep study questionnaire administered? ADMINISTERED
1=Self-administered, 2=Administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) ___/___/ COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ ENTER_DT

Username of person entering this form ENTER_USER

Revision of 01/10/2019 PVD_SLEEP_TRANS

PVDOMICS

PVDOMICS STUDY
Clinical Center Sleep Study
Download and File Transmission - Form #152

Instructions: Complete this form after the sleep monitoring device given to participant (as per F150) is returned or the study personnel learns that the device will not be returned.

PID [| | | | | |] [AC] [| | | | | | | |] VISIT_DT

1. Identification Number 2. Alphacode 3. Start date of when device placed: (mm/dd/yyyy)

4. Did participant return device and all device components? (0=No, 1=Yes) ..... RETURN_EQUIP
5. Date participant returned device (mm/dd/yyyy) ..... __ __/__ __/RETURN_DT
6. Did participant return completed sleep questionnaire? (0=No, 1=Yes)..... RETURN_QUES __
7. Did participant attempt to complete the sleep study? ..... COMP_STUDY __
(0=No, not attempted, no file to transfer, 1=Yes, study completed, 2=Yes, study attempted but not completed)

a. If Q7 = 0 or 2, primary reason participant did not attempt/complete sleep study? ..... COMP_STUDY_RSN __

1=Could not get equipment hooked up correctly according to directions provided
2=Could not get equipment hooked up correctly even with family member assistance
3=Device components caused discomfort and/or fell off during the night
4=Unable to sleep while wearing device
5=Acute onset of medical condition prevented study from being attempted (i.e., cold, bronchitis, other)
6=Participant refused to do test
8=Other, specify in comments

Note: If there is no file to transfer, skip to Q14.

8. Does the ID on the recording match questionnaire id on Form 151? (0=No, 1=Yes) ..... ID_MATCH __
9. Are there signals on each of the channels (for example, no flat lines)? (0=No, 1=Yes)..... SIGNALS __
10. Are there <u>at least 3 hours</u> recorded oximetry measurements? (0=No, 1=Yes)..... OXIMETRY __
11. Are there <u>at least 3 hours</u> of recorded data downloaded? (0=No, 1=Yes) ..... DOWNLOADED
12. File converted to EDF format with correct participant id, alphacode, and start date? (0=No, 1=Yes) CONVERTED
13. Date file transmitted to Sleep Core (mm/dd/yyyy) ..... __ __/__ __/TRANS_DT
14. Comments for Sleep Core personnel: _____ COMMENTS

_____

_____

15. Date of initialization, demo, and (*if done on same day*) placement: (mm/dd/yyyy) ..... __ __/VIST_DT_F150
Note: Q15 <u>must match</u> the date recorded on F150, Q3a.

198. Username* of PVDOMICS staff member checking in device ..... CHECKIN_USER
199. Username* of PVDOMICS staff member transmitting EDF to Core..... TRANS_USER
**Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu*
200. Date form completed (mm/dd/yyyy)..... __ __/__ __/COMP_DT
201. Username of person reviewing completeness of this form ..... __ __ COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/ENTER_DT

Username of person entering this form __ __ ENTER_USER

PVD_SLEEP_RECEIPT

PVDOMICS

PVDOMICS STUDY
Sleep Study Core Receipt and QA Review - Form #153

Instructions: This form is completed by PVDOMICS Sleep Study Core personnel upon receipt and review of EDF file transmitted from a clinical center.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number

AC [ ][ ] 2. Alphacode

VISIT [ ][ ][ ][ ][ ][ ][ ][ ] 3. Start date of when device placed: (mm/dd/yyyy)

4. Date file received at Sleep Core and opened for review? (mm/dd/yyyy) ___ ___/___ ___/ FILE_DT

5. Was sleep data available and test able to be scored? (0=No, 1=Yes) ..... SCORED

If no, why couldn't test be scored? (0=No, 1=Yes)

a. Not enough data recorded ..... LACKS_DATA

b. Not enough oximetry data recorded ..... OXI_DATA

c. Appears that equipment failed during the test ..... EQUIP_FAIL

d. EDF file got corrupted while downloading from device or during transmission ..... EDF

Scoring

6. Date sleep study scored? (mm/dd/yyyy) ..... ___ ___/___ ___/ SCORE_DT

7. Username of Sleep Core Scorer ..... ___ ___ ___ SCORE_USER

8. Time Scorer set lights <u>off</u> (24-hr clock) (hh:mm) ..... OFF:_TM

9. Time Scorer set lights <u>on</u> (24-hr clock) (hh:mm) ..... ON:TM

10. Total recording time (24-hour clock) (hh:mm) ..... TOTAL_TM

11. Total participant sleep time (24-hour clock) (hh:mm) ..... SLEEP_TM

12. Number of apnea and hypopnea events identified ..... EVENT_CT

Database will calculate Q13 and Q14. Record calculated scores in space provided below.

13. Calculated AHI score (events/hour of sleep) ... AHI_SCORE ___ ___ ___ . ___

14. Calculated Apnea Hypopnea Index (AHI) severity score .. SEVERITY_SCORE

The AHI severity scores are categorized as: 1=Normal: 0-4, 2=Mild sleep apnea: 5-14, 3=Moderate sleep apnea: 15-29, 4=Severe sleep apnea: 30 or more

Scoring continued on next page

For Channels Identified Below - Code the following:

Column a: use: 0=No, 1=Yes
Column b: record number of hours of usable data to the nearest 15 minutes
Column c: 1 = <25% of estimated sleep time, 02 = 25-49% of estimated sleep time, 3 = 50-74% of estimated sleep time, 4 = 75-94% of estimated sleep time, 5 = Entire estimated sleep time (>95%)

	a. Channel Available?	b. Usable Signal Hours?	c. Signal Quality Code
15. Cannula flow/pressure?	CANN_AVAIL	CANN_HRS	CANN_CODE
16. Thoracic chest belt	CHEST_AVAIL	CHEST_HRS	CHEST_CODE
17. Abdominal belt	ABD_AVAIL	ABD_HRS	ABD_CODE
18. Oximetry?	OXI_AVAIL	OXI_HRS	OXI_CODE
19. ECG?	ECG_AVAIL	ECG_HRS	ECG_CODE
20. PAP therapy?	PAP_AVAIL		

For Questions 20-21: use the following scores: 1 = <25% of estimated sleep time, 2 = 25-49% of estimated sleep time, 3 = 50-74% of estimated sleep time, 4 = >75% of estimated sleep time

21. Flow limitation score: FLOW_SCORE

22. Overall sleep study quality SLEEP_QUALITY
    1=Fail. Less than 3 hours of oximetry and one band
    2=Fair. Oximetry and either nasal/mask pressure or one band usable for ≥ 3 hours
    3=Good. At least nasal/mask pressure, one band, and oximetry usable for ≥ 4 hours
    4=Excellent. All channels are useable for ≥ 4 hours but < 6 hours.
    Comments: SLEEP_COMMENTS

Urgent Alerts:

23. Were there any urgent alerts identified? (0=No, 1=Yes, complete Form 154) ALERTS

24. Date reviewed with Sleep Core PI (mm/dd/yyyy) PI_REVW_DT

200. Date form completed (mm/dd/yyyy) COMP_DT

201. Username of person reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT

Username of person entering this form ENTER_USER

PVD_SLEEP_FINDINGS

PVDOMICS

PVDOMICS STUDY
Sleep Study Core Incidental Finding(s) Form #154

Data on this form is collected by the Sleep Core when an incidental finding(s) has been identified on a participant's sleep study recording(s). This form will be entered in the PVDOMICS database by the Sleep Core personnel and an email message will automatically be sent to the Clinical Center PI and Study Coordinator. A Form 138 will need to be completed by the local site to acknowledge receipt of these findings.

PID						AC		VISIT_DT							

1. Identification Number 2. Alphacode 3. Date sleep study started (mm/dd/yyyy)

4. Date file received at Sleep Core (mm/dd/yyyy) ..... __ __ / __ __ / FILE_DT
5. Date sleep study scored at Sleep Core (mm/dd/yyyy)..... __ __ / __ __ / SCORE_DT
6. Username of polysomnologist who identified findings ..... SCORE_USER

Findings:

7. Abnormal apnea hypopnea index (AHI) > 50? (0=No, 1=Yes) ..... AHI
8. Oxyhemoglobin saturation during sleep <85% for greater than 10% of the estimated sleep time? (0=No, 1=Yes)..... OXYHGB
9. Other urgent specific heart rate or ECG finding? (0=No, 1=Yes)..... OTH_ECG_FINDINGS
   a. Supraventricular tachycardia sustained for 30 seconds or greater with heart rate > 150 bpm? (0=No, 1=Yes) ..... TACH
   b. Marked bradycardia? (30 bpm for 6 seconds or greater) (0=No, 1=Yes) ... BRADY
   c. Wide QRS tachycardia? (>4 beats with rate >100 bpm) (0=No, 1=Yes) ... QRS_TACH
   d. Second degree AV block Mobitz Type II, high grade AV block? (0=No, 1=Yes) AV_BLOCK_2
   e. Third degree atrioventricular block?..... AV_BLOCK_3
   f. Atrial fibrillation/atrial flutter with rate >150 bpm? (0=No, 1=Yes) ... ATRIAL_FIB
   g. Sinus pauses >3 seconds? (0=No, 1=Yes) ..... SINUS_PAUSE
10. Comments:

11. a. Date of review with Sleep Core PI (mm/dd/yyyy)..... __ __/ PI_REVW_DT
    b. Username of Sleep Core PI ..... __ PI_USERNAME

12. Has someone at the Sleep Core spoken to someone at the center? CONTACTED
    (0=No, not necessary, 1=Yes) .....
    a. Date contacted (mm/dd/yyyy)..... __ __/CONTACTED_DT
    b. Sleep Core personnel spoke to? ..... CONTACTED_PERSON
    1=PVDOMICS PI
    2=PVDOMICS Co-PI
    3=Other Physician
    4=PVDOMICS Study Coordinator
    5=Other clinical center person

Name of person contacted: (not entered into database):

200. Date form completed (mm/dd/yyyy)..... __ __/__ __/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date form entered (mm/dd/yyyy) __ __/__ __/ ENTER_DT

Username of person entering this form ENTER_USER

PVD_SLEEP_HIST_TRANS

Revision of 04/04/2018

PVDOMICS

PVDOMICS STUDY
Clinical Center Alternative Sleep Study
Report Transmission - Form #155

Instructions: This form is completed by clinical center personnel to document a historical or current clinical sleep study that did not follow PVDOMICS protocol. A historical sleep study report can be used if it is less than one year from date of initial PVDOMICS study enrollment and with no change in nighttime oxygen or sleep disorder therapy, no more than 10% weight loss or gain, and in the opinion of the investigator, no change in patient condition that would impact results, then the clinically available data may be considered adequate for inclusion in the case. Contact the Sleep Study Core if you have any questions.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number

[AC] 2. Alphacode

[ ][ ][ ][ ][ ][ ][ ][ ] VISIT_DT 3a. Start date of alternative sleep study: (mm/dd/yyyy)

3. b. Type of study ..... STUDY_TYPE
(1=Historical, 2=Current clinical (not following PVDOMICS protocol) *(if Q3b =2, skip to Q6).*

4. a. Does PVDOMICS study staff know if there has been a change in nighttime oxygen or sleep disorder therapy since this **historical** study was completed? ..... CHG_THER
0=No (no change in nighttime oxygen or sleep disorder therapy since historical study completed)
1=Yes (a change in nighttime oxygen or sleep disorder therapy was identified since historical study completed)
9=Unknown (unknown if any changes to therapy since historical study completed)

b. Does PVDOMICS study staff know if there has been a 10% change in weight since this **historical** study was completed? ..... CHG_WT
0=No, participant reports no 10% change in weight since historical study completed
1=Yes, participant reports that there was a weight gain of more than 10% since the historical study was completed
2=Yes, participant reports that there was a weight loss of more than 10% since the historical study was completed
9=Unknown whether or not there was 10% weight gain or loss.

5. Does center physician think there is a change in the participant's clinical condition that would impact results from the historical study? ..... IMPACT
0=No, center physician does not believe there is a change in participant's clinical condition that would have an impact on historical study results
1=Yes, center physician does believe there is a change in participant's clinical condition that impacts historical study results

6. Date final report transmitted to Sleep Core (mm/dd/yyyy) ..... __ __/__ __/ TRANS_DT

7. Comments for Sleep Core personnel: _____ COMMENTS

_____

_____

199. Username* of PVDOMICS staff member transmitting report to Core ..... TRANS_USER
**Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)*

200. Date form completed (mm/dd/yyyy) ..... __ __/__ __/ COMP_DT

201. Username of person reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/ ENTER_DT

Username of person entering this form ENTER_USER

PVD_SLEEP_HIST_REV

PVDOMICS

PVDOMICS STUDY
Alternative Sleep Study
Core Review - Form #156

Instructions: This form is completed by Sleep Study Core personnel following review of historical or current clinical sleep study data.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number

AC [ ][ ] 2. Alphacode

VISIT_DT [ ][ ][ ][ ][ ][ ][ ][ ] 3a. Date sleep study started (mm/dd/yyyy)

3. b. Type of study ..... STUDY_TYPE
(1=Historical limited, 2=Historical full PGS, 3=Current clinical limited, 4=Current clinical full PSG)

4. Date sleep study report of findings reviewed by Core (mm/dd/yyyy) .... ___ ___ / REVIEW_DT

5. Username* of PVDOMICS Core staff member reviewing data ..... ___ ___ REVIEWER

Respiration Indices

6. Apnea Hypopnea Index (AHI) score (events/hour of sleep) ..... AHI ___.___
(AHI breakdown: Normal=0-4, Mild=5-14, Moderate=15-29, Severe=30 or more)

7. Central Apnea Index ..... CENT_APNEA_INDEX

8. Apnea Index (events/hour of sleep) ..... APNEA_INDEX

9. Hypopnea Index (events/hour of sleep) ..... HYPOPNEA_INDEX

10. Obstructive apnea (total number of events) ..... OBST_APNEA_EVEN

11. Central apnea (total number of events) ..... CENT_APNEA_EVEN

12. Hypopneas (total number of events) ..... HYPOPNEA_EVEN

Saturation

13. Oxygen Desaturation Index (ODI) (events/hour) ..... ODI ___ ___ ___.___

14. Lowest SpO2 (%) ..... SPO2_LOWEST

15. Average SpO2 (%) ..... SPO2_AVERAGE

16. Desaturation <90% (total number of events/hour of sleep) ..... DESAT_LESS90

17. Desaturation <85% (total number of events/hour of sleep) ..... DESAT_LESS85

18. SpO2 time <90 (%) ..... SPO2_TIME_LESS90

19. SpO2 time <85 (%) ..... SPO2_TIME_LESS85

Time

20. Total sleep time (total minutes)..... SLEEP_TM_TOTAL
21. Total recording time (total minutes)..... RECORD_TM_TOTAL

Pulse

22. Average pulse rate (bpm)..... PULSE_AVERAGE
23. Highest pulse rate (bpm)..... PULSE_HIGHEST
24. Lowest pulse rate (bpm)..... PULSE_LOWEST

25. Based on the sleep data reviewed, what is the adequacy/quality of this historical study? ADEQUACY
    0=Historical study is inadequate for the purposes of PVDOMICS study; a new sleep study is recommended
    1=Study is adequate

26. If Q25=1, what is the result of this sleep study? ..... STUDY_RESULT
    1=Result is considered normal (0-4)
    2=Participant has mild sleep apnea (5-14)
    3=Participant has moderate sleep apnea (15-29)
    4=Participant has severe sleep apnea (≥30)

27. Comments from Sleep Core: _____ COMMENTS
    _____
    _____

28. Date results reviewed with Sleep Core PI (mm/dd/yyyy)..... PI_REVIEW_DT

200. Date form completed (mm/dd/yyyy)..... __/__/ COMP_DT
201. Username of person reviewing completeness of this form..... COMP_USER

Core Use Only

Date Form Entered (mm/dd/yyyy) __/__/ ENTER_DT
Username of person entering this form ENTER_USER

PVD_SF36

Revision of 05/25/2016

PVDOMICS

PVDOMICS STUDY
Survey Instrument (SF-36 v2) Form # 170E

PID | AC | VISIT_DT

1. Identification Number	2. Alphacode	3. Date of survey: mm/dd/yyyy

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

4. In general, would you say your health is: HEALTH_GEN

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>? HEALTH_1YR

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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(SF-36v2® Health Survey Standard, United States (English))

6. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports VIGOROUS	☐ 1	☐ 2	☐ 3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf MODERATE	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries LIFTING	☐ 1	☐ 2	☐ 3
d Climbing <u>several</u> flights of stairs STAIRS-N	☐ 1	☐ 2	☐ 3
e Climbing <u>one</u> flight of stairs STAIRS-1	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping BKS	☐ 1	☐ 2	☐ 3
g Walking <u>more than a mile</u> WALK-1MI	☐ 1	☐ 2	☐ 3
h Walking <u>several hundred yards</u> WALK-100YARDS-N	☐ 1	☐ 2	☐ 3
i Walking <u>one hundred yards</u> WALK-100YARDS-1	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself BATH-DRESS	☐ 1	☐ 2	☐ 3

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7. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PHY-CUT
PHY-LESS
PHY_LIMITED
PHY-DIFF

8. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

EMT_CUT
EMT_LESS
EMT_SKIP

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(SF-36v2® Health Survey Standard, United States (English))

9. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

INTERFER

10. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PAIN - AMOUNT

11. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PAIN - INTERFER

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12. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5 PEP
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4 NERVOUS	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4 DOWN	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4 CALM	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4 ENERGY	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4 DEPRESSED	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4 WORN-OUT	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4 HAPPY	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4 TIRED	☐ 5

13. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4 DURATION	☐ 5

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(SF-36v2® Health Survey Standard, United States (English))

14. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4 SICK-EASIER	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4 SAME	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4 WORSE	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4 EXCELLENT	☐ 5

Thank you for completing these questions!

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(SF-36v2® Health Survey Standard, United States (English))

PVD_SF36

Revision 09/13/2016

PVDOMICS

PVDOMICS STUDY
Administration Form
Questionnaire Spanish Version

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry. Make sure to label this page with identifying patient and visit information.

PID | | | | | | | AC | | VISIT_DT | | | | | | | |

1. Identification Number | 2. Alphacode | 3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this survey administered? ADMINISTERED
1=Self-administered, 2=Interview-administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) ___/___/COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ENTER_DT

Username of person entering this form ENTER_USER

PVD_MINN_LIVING

Revision 04/05/2016

PVDOMICS

PVDOMICS STUDY
MINNESOTA LIVING WITH HEART FAILURE®
QUESTIONNAIRE Quality of Life Form #171

1. Identification Number	2. Alphacode	3. Date questionnaire completed (mm/dd/yyyy)

Instructions: The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by:	**No**			**Very Little**		**Very Much**
1. Causing swelling in your ankles or legs?	0	1	2	SWELLING 3	4	5
2. Making you sit or lie down to rest during the day?	0	1	2	REST 3	4	5
3. Making your walking about or climbing stairs difficult?	0	1	2	WALK 3	4	5
4. Making your working around the house or yard difficult?	0	1	2	YARD 3	4	5
5. Making your going places away from home difficult?	0	1	2	TRAVEL 3	4	5
6. Making your sleeping well at night difficult?	0	1	2	SLEEP 3	4	5
7. Making your relating to or doing things with your friends or family difficult?	0	1	2	FRIENDS 3	4	5
8. Making your working to earn a living difficult?	0	1	2	WORKING 3	4	5
9. Making your recreational pastimes, sports or hobbies difficult?	0	1	RECREATION 2	3	4	5
10. Making your sexual activities difficult?	0	1	2	SEX 3	4	5

Continue on to next page

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PVDOMICS

PVDOMICS STUDY
MINNESOTA LIVING WITH HEART FAILURE®
QUESTIONNAIRE Quality of Life Form #171

	No	Very Little				Very Much
11. Making you eat less of the foods you like?	0	1	2	3 EAT	4	5
12. Making you short of breath?	0	1	2	3 BREATH	4	5
13. Making you tired, fatigued, or low on energy?	0	1	2	3 TIRED	4	5
14. Making you stay in a hospital?	0	1	2	3 HOSPITAL	4	5
15. Costing you money for medical care?	0	1	2	3 MONEY	4	5
16. Giving you side effects from treatments?	0	1	2 SIDE-EFFECTS	3	4	5
17. Making you feel you are a burden to your family or friends?	0	1	2	3 BURDEN	4	5
18. Making you feel a loss of self-control in your life?	0	1	2 CONTROL	3	4	5
19. Making you worry?	0	1	2	3 WORRY	4	5
20. Making it difficult for you to concentrate or remember things?	0	1	2 REMEMBER	3	4	5
21. Making you feel depressed?	0	1	2 DEPRESSED	3	4	5

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PVD-MINN_LIVING

PVDOMICS

PVDOMICS STUDY
MINNESOTA LIVING WITH HEART FAILURE®
QUESTIONNAIRE Quality of Life Form #171

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry.
Make sure to label this page with identifying patient and visit information.

PID | AC | VISIT-DT

1. Identification Number | 2. Alphacode | 3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this survey administered? ADMINISTERED
1=Self-administered, 2=Interview-administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) ___/___/COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ENTER_DT

Username of person entering this form ENTER_USER

Revision 07/12/2016

PVD_MINN_LIVING

Form #171
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Administration Form for MLHF Questionnaire
Spanish Version

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry.
Make sure to label this page with identifying patient and visit information.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this survey administered? ADMINISTERED
1=Self-administered, 2=Interview-administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) ___/___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ ENTER_DT

Username of person entering this form ENTER_USER

PVD - EMPHASIS

Revision 04/08/2016

PVDOMICS

PVDOMICS STUDY
EmPHasis-10 Quality of Life Form #172

1. Identification Number	2. Alphacode	3. Date questionnaire completed (mm/dd/yyyy)

This questionnaire is designed to determine how pulmonary hypertension (PH) affects your life. Please answer every question by placing an "X" over the ONE NUMBER that best describes your recent experience of living with PH.

For each item below, place an "X" in the box that best describes your experience.

I am not frustrated by my breathlessness	FRUSTRATED 0 1 2 3 4 5	I am very frustrated by my breathlessness
Being breathless never interrupts my conversations	INTERRUPTS 0 1 2 3 4 5	Being breathless always interrupts my conversations
I do not need to rest during the day	REST 0 1 2 3 4 5	I always need to rest during the day
I do not feel exhausted	EXHAUSTED 0 1 2 3 4 5	I always feel exhausted
I have lots of energy	ENERGY 0 1 2 3 4 5	I have no energy at all
When I walk up one flight of stairs I am not breathless	STAIRS 0 1 2 3 4 5	When I walk up one flight of stairs I am very breathless
I am confident out in public places/crowds despite my PH	CROWDS 0 1 2 3 4 5	I am not confident at all in public places/crowds because of my PH
PH does not control my life	CONTROL 0 1 2 3 4 5	PH completely controls my life
I am independent	INDEPENDENT 0 1 2 3 4 5	I am completely dependent
I never feel like a burden	BURDEN 0 1 2 3 4 5	I always feel like a burden

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PVDOMICS

PVDOMICS STUDY
EmPHasis-10 Quality of Life Form #172

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry.

Make sure to label this page with identifying patient and visit information.

PID | AC | VISIT-DT

1. Identification Number | 2. Alphacode | 3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this survey administered? ADMINISTERED
1=Self-administered, 2=Interview-administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) __/__/ COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __/__/ ENTER_DT

Username of person entering this form ENTER_USER

Revision 07/12/2016

PVD_EMPHASIS

Form #172
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Administration Form for emPHasis-10
Questionnaire Spanish Version

Coordinator Instructions: If this form is being completed (self-administered) by the participant, please remove this page from the form while the participant has the form. Re-attach this page prior to data entry.
Make sure to label this page with identifying patient and visit information.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date questionnaire completed (mm/dd/yyyy)

100. a. How was this survey administered? ADMINISTERED
1=Self-administered, 2=Interview-administered in person, 3=Interview by telephone

b. If Q100a = 2 or 3, enter the username of the person administering the form ADMIN_USER

101. Setting where this form was completed? SETTING
1=At clinic visit, 2=Other clinical setting, 3=At home

102. In what language was this instrument completed? LANG
1=English, 2=Spanish

200. Date this form completed (mm/dd/yyyy) ___/___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ___/___/ ENTER_DT

Username of person entering this form ENTER_USER

Revision 10/01/2018

PVD_PHONE_ACCESS

PVDOMICS

PVDOMICS STUDY
Two-Week Event Assessment - Form #185

Coordinator Instructions: This form is to be completed two weeks after a participant has completed the PVDOMICS study*. The participant is to be contacted and asked the following questions. If a participant has been to the emergency room, hospital or had an unscheduled medical appointment, please obtain the information needed to complete the appropriate adverse or serious adverse event research form.

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of contact: (mm/dd/yyyy)

Health-related Participant Questions:

4. Have you (the participant) been hospitalized? (0=No, 1=Yes) ..... HOSPITALIZED
5. Have you (the participant) been to the Emergency Room or Department (0=No, 1=Yes) ..... ER
6. Have you (the participant) had an unscheduled doctor visit? (0=No, 1=Yes, explain in comments) UNSCHED_DOC

7. **Brief Comments** *(enter into database. Recall that Forms 400 & 401 must be completed if unanticipated AE or if SAE.)* BRIEF_COMMENTS

Other Participant Question:

8. May we contact you again for future studies? ..... FUTURE_CONTACT
(0=No, 1=Yes, 8=N/A-did not speak directly with participant)

Coordinator Use only

100. Who did coordinator contact in order to obtain AE/SAE information? ..... COORD_SPEAK
1=Participant (recommended), 2=Family member/Significant other, 8=Other

a. Was Spanish translator used to 'speak' with participant? (0=No, 1=Yes) .... SPANISH_TRANS

101 If, after contacting someone other than participant, did participant die within the previous two weeks since last PVDOMICS visit? (0= No, 1= Yes) ..... DEATH
(if yes, Forms 400 and 401 should be completed as soon as possible)

b. Date of death (mm/dd/yyyy) ..... __ __/__ __/DEATH_DT

200. Date form completed (mm/dd/yyyy) ..... __ __/__ __/COMP_DT

201. Username of person reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/ENTER_DT

Username of person entering this form ENTER_USER

* *Effective July 1, 2017, use this form for participants currently enrolled in PVDOMICS.*

Revision of 10/02/2018

PVD_ANNUAL_FUP

Form #187
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Annual Follow-up - Form #187

Instructions: It is important to determine the vital status of each participant and a form should be completed for all participants unless already known to have expired. This form should be completed annually based on the participant's date of enrollment.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number

AC [ ][ ] 2. Alphacode

VISIT_DT [ ][ ]/[ ][ ]/[ ][ ][ ][ ] 3. Status Date: mm/dd/yyyy

4. a. Vital Status (0=Dead, 1=Alive, *skip to Q5a*, 9=Unknown, *skip to Q5a*) ..... VITAL_STATUS

b. Date of death (mm/dd/yyyy) ..... __ __/__ __/DEATH_DT

c. Reported cause of death:

	Cause(s) of Death	MedDRA *Autopopulated*
4c1. Primary Cause:	*(Note: A procedure code cannot be a primary cause of death.* CAUSE_PRIM_DESC	CAUSE_PRIM
4c2. Secondary Cause:	CAUSE_SEC_DESC	CAUSE_SEC

5. a. Did participant receive a transplant? (0=No, 1=Yes, 8=N/A-healthy control, 9=Unknown, skip to Q6) ..... TRANSPLANT

b. If yes, date of transplant (mm/dd/yyyy) ..... __ __/__ __/TRANSPLANT_DT

c. Type of transplant ..... TRANSPLANT_TYPE

1=Single lung only
2=Double-lung
3=Lung, unknown whether single or double
4=Heart only
5=Heart and lung
6=Other, specify: TRANSPLANT_OTH
9=Unknown

6. Comments: *(enter into database).* COMMENTS

7. How was status determined? ..... STATUS_METHOD

1=Spoke with participant
2=Spoke with participant's family member/friend
3=Follow-up visit to clinical center
4=Local physician's office contacted
8=Other: specify: METHOD_OTH

200. Date this form completed (mm/dd/yyyy) ..... __ __/__ __/COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/ENTER_DT

Username of person entering this form ENTER_USER

PVD_CBC

Revision of 08/22/2017

PVDOMICS

PVDOMICS STUDY
Center CBC w Diff Results Form #200

Instructions: This form is used to capture lab results completed at local site. Report only those tests completed on the same day. If additional blood is collected, report those results on a separate Form #200.

Note: Lab draw must be no more than 1 month before the Form 100 date.

PID | AC | VISIT_DT

1. Identification Number
2. Alphacode
3. Date blood drawn (mm/dd/yyyy)

4. Historical data used? (0=No, 1=Yes) HISTORICAL ____

5. How was WBC differential analyzed? (1=Machine, 2=Manual [Staff review], 9=Unknown) DIFF_METHOD ____

CBC Results

6. Total WBC (K/ul) WBC ___ ___.___ ___
7. Red Blood Cell Count (RBC) (M/ul) RBC ___ ___.___ ___
8. Red Cell Distribution Width (RDW) (%) RDW ___ ___.___
9. Hemoglobin (g/dL) HGB ___ ___.___
10. Hematocrit (%) HCT ___ ___.___
11. Platelet count (K/ul) PLT ___ ___ ___
12. Mean Platelet Volume (MPV) (fL) MPV ___ ___.___
13. Mean Corpuscular Volume (MCV) (fL) MCV ___ ___ ___.___

Note: Database will calculate 14, 15, 16b, 17b, 18b 19b and 20b automatically. Write the values in the greyed out boxes on this paper form.

14. Mean Corpuscular Hemoglobin (MCH) (pg) MCH ___ ___.___
15. Mean Corpuscular Hemoglobin Concentration (MCHC) (g/dL) MCHC ___ ___.___

PVD_CBC

WBC Differential

16. a. Absolute Neutrophils (ANC) (K/uL) NEUT_ANC ___.___
    b. Neutrophils (%) NEUT ___.___
17. a. Absolute Lymphocytes (K/uL) ABS_LYMPHS ___.___
    b. Lymphocytes (%) LYMPHS ___.___
18. a. Absolute Monocytes (K/µL) ABS_MONO ___.___
    b. Monocytes (%) MONO ___.___
19. a. Absolute Basophils (K/µL) ABS_BASO ___.___
    b. Basophils (%) BASO ___.___
20. a. Absolute Eosinophils (K/µL) ABS_EOSIN ___.___
    b. Eosinophils (%) EOSIN ___.___

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

Clinical Center Use Only
Date form entered (mm/dd/yyyy) ENTER_DT __/__/____
Username of person entering this form ENTER_USER ___

CC_N: Clinical Center #

PVD_CMP

PVDOMICS

PVDOMICS STUDY
Center Complete Metabolic Panel (CMP)
Results Form #201

Instructions: One Clinical Center CMP results is expected. The results recorded on this form must all be from the same blood collection date documented in Q3: If some results are from a different date, complete an additional Form 201 using that date.

Note: Lab draw must be no more than one month before the Form 100 date.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number [AC] 2. Alphacode [ ][ ][ ][ ][ ][ ][ ][ ] 3. a. Date blood drawn (mm/dd/yyyy) VISIT_DT COLL_TM

4. a. Did participant fast prior to blood collection? (0=No, 1=Yes, 2=Historical) ..... FASTING
   b. How many hours prior to collection did participant fast? ..... FAST_HRS
5. Date sample analyzed (mm/dd/yyyy) ..... __ __/__ __/ ANALYZED_DT

CMP Results

6. Total protein (g/dL) ..... TPROT
7. Albumin (g/dL) ..... ALB
8. Calcium (mg/dL) ..... CA
9. Total bilirubin (mg/dL) ..... TBILI
10. Alkaline phosphatase (U/L) ..... __ ALKP
    (Use the single space to indicate "<" or ">")
11. Aspartate aminotransferase (AST) (U/L) ..... __ AST
    (Use the single space to indicate "<" or ">")
12. Alanine aminotransferase (ALT) (U/L) ..... __ __ ALT
    (Use the single space to indicate "<" or ">")
13. Glucose (mg/dL) ..... GLUC
14. Blood urea nitrogen (BUN) (mg/dL) ..... BUN
15. a. Serum Creatinine (mg/dL) ..... CR
    Calculated eGFR (mL/min/1.73 m^2) ..... EGFR

16. Sodium (mmol/L) ..... NA

17. Potassium (mmol/L) ..... K

18. Chloride (mmol/L) CL

19. CO2 (mmol/L) CO2

20. Anion Gap (mmol/L) ..... ANION_GAP

200. Date form completed (mm/dd/yyyy) ..... _ _/_ _/ COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

Clinical Center Use Only

Date form entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT

Username of person entering this form ENTER_USER

Revision of 02/23/2018 PVD_ANA

PVDOMICS

PVDOMICS STUDY
Clinical Center Antinuclear Antibody (ANA)
Results Form #202

Instructions: One Clinical Center serum ANA test result is expected. The results should be a ratio. This form is completed as part of the data collection process when the clinical center team has results for all tests listed. The results recorded on this form must all be from the same blood collection date documented in Q3. If some results are from a different date, complete an additional Form 202 using that date.

Note: Lab draw must be no more than 45 days before the Form 100 date.

PID | AC | VISIT_DT, COLL_TM

1. Identification Number | 2. Alphacode | 3a. Date blood drawn (mm/dd/yyyy)

3. b. Historical data used? (0=No, 1=Yes) ..... HISTORICAL ___

4. Was ANA obtained by indirect fluorescent antibody (IFA)? (0=No, 1=Yes) ..... ANA ___

a. If yes, Titer ..... TITER ___

1=1:80	4=1:640	7=1:>2560
2=1:160	5=1:1280	8=Negative result/trace
3=1:320	6=1:260	9=1:40

b. What is the pattern? ..... PATTERN ___

1=Homogenous	4=Centromere	7=Combination
2=Speckled	5=Rim	(specify:_____)
3=Nuclear	6=Diffuse	8=Other

5. Was ANA obtained by immunoassay (0=No, 1=Yes) ..... IMMUNOASSAY ___

a. If yes, what was ANA value (OD Ratio)? ..... ANA_VALUE ___.___

(If negative or trace, enter 0.0)

200. Date form completed (mm/dd/yyyy) ..... ___ ___/___ ___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... ___ ___ COMP_USER

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ___ ___/___ ___/ ENTER_DT

Username of person entering this form ___ ENTER_USER

PVD_HIV

Revision of 06/23/2017

Form #203
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Clinical Center HIV Antigen/Antibody Screen
Results Form # 203

Instructions: One test result per participant is expected.

- If participant has a previously positive HIV screen, that result is acceptable and there is no need to repeat the screen.
- If participant has a previously negative HIV screen completed within the past year, that result is acceptable and there is no need to repeat the screen.

PID

1. Identification Number

AC

2. Alphacode

VISIT_DT

3. Date of HIV screen blood collected (mm/dd/yyyy)

4. Historical data used? (0=No, 1=Yes) ..... HISTORICAL ___

5. Results of HIV test (0= Nonreactive/negative, 1= Reactive/positive) ..... HIV ___

200. Date form completed (mm/dd/yyyy) ..... COMP_DT ___ ___/___ ___/___ ___ ___ ___

201. Username of person completing/reviewing completeness of this form..... COMP_USER _____

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ENTER_DT _____

Username of person entering this form ENTER_USER

CC_N

PVDOMICS

PVDOMICS STUDY
Clinical Center Hepatitis Screen Results Form # 204

Instructions: One test result per participant is expected.

- If participant has a previously positive hepatitis screen, that result is acceptable and there is no need to repeat the screen.
- If participant has a previously negative hepatitis screen completed within the past year, that result is acceptable and there is no need to repeat the screen.

PID | AC | VISIT_DT , COLL_TM

1. Identification Number
2. Alphacode
3. Date blood collected (mm/dd/yyyy)

4. Historical data used? (0=No, 1=Yes) ..... HISTORICAL__
5. Hepatitis B Core Antibody (0=Negative, 1=Positive) ..... ANTI_HB_CORE
6. Hepatitis C Antibody (0=Negative, 1=Positive) ..... ANTI_HC ___
7. Hepatitis B surface Antigen (0=Negative, 1=Positive) ..... HBSAG ___
8. Hepatitis B surface Antibody (0=Negative, 1=Positive, 2=Not obtained, 3=Indeterminate) ANTI_HB_SURFACE

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

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ___ ___/___ ___/ ENTER_DT

Username of person entering this form ___ ENTER_USER

PVD_PT

Revision of 06/23/2017

PVDOMICS

PVDOMICS STUDY
Clinical Center Prothrombin Time Results Form #205

Instructions: This form is used to capture prothrombin time results completed at a clinical center. Report only the test completed on the same day. If additional blood is collected, report those results on a separate Form #205.

Note: Lab draw must be on or after the Form 100 date.

PID | AL | VISIT_DT

1. Identification Number
2. Alphacode
3. Date blood drawn (mm/dd/yyyy)

4. PT Sec (sec) ..... PT ____.__

5. PT INR – (International Normalized Ratio) ..... PT_INR ___.__

200. Date form completed (mm/dd/yyyy) ..... COMP_DT __/__/____

201. Username of person completing/reviewing completeness of this form... COMP_USER _____

Clinical Center Use Only

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

Username of person entering this form ENTER_USER

CC-N

Revision of 11/10/2017

PVD_ABG

Form #207
Page 1 of 2

PVDOMICS

PVDOMICS STUDY
Center Arterial Blood Gases (ABG) Form #207

Instructions: Complete this form if blood was drawn for arterial blood gases (ABG) measures. *Although ABG's are not required by protocol, ABGs may be captured during the course of study visits and if so, the PVDOMICS study would like to obtain these results. Please complete and enter this form even if ABG's are not done.*

PID | | | | | | | AC | | VISIT_DT | | | | | | | |

1. Identification Number
2. Alphacode
3. Date of ABG collection (mm/dd/yyyy)

4. Was arterial blood drawn for ABG's? (0=No, skip to end of form, 1=Yes, continue to Q5) ..... BLOOD_DRAWN

5. When was ABG measured? ..... ABG_MEAS
   1=At time of PFTs completed for PVDOMICS study
   2=At time of RHC only
   3=At time of invasive CPET (includes RHC)
   4=Other, specify *(not entered)*: _____

6. Using supplemental oxygen at the time blood drawn for ABG's? (0=No, skip to Q7, 1=Yes) ..... SUP_OXYGEN
   a. If yes, how was oxygen delivered? ..... DELIV_METHOD
      1=Nasal Cannula
      2=Nasal Cannula with a reservoir
      3=Venturi mask/trach collar
      4=Non-rebreather mask
      1. If Q6a = 2, was participant switched to a nasal cannula prior to drawing blood? ..... NASAL_CAN
   b. What was range of O_2 use reported by participant? ..... OXYGEN_RANGE
      1=0 to <2 L/m
      2=2 to <4 L/m
      3=4 to <6 L/m
      4=6 to 8 L/m
      5=> 8 L/m

7. Device used to obtain arterial blood (1=Syringe, 2=Arterial line) ..... DEVICE
8. pH (pH units) ..... PH
9. pCO2 (mmHg) ..... PCO_2
10. pO2 (mmHg) ..... PO_2
11. Bicarbonate (HCO_3) (mmol/L) ..... HCO_3
12. Carboxyhemoglobin (HbCO) (%) ..... HBCO, HBCO_SIGN
    (Use the single space to indicate "<" or ">")
13. Methemoglobin (MetHb) (%) ..... METHB_SING, METHB
    (Use the single space to indicate "<" or ">")
14. Oxygen Saturation (O_2Sat) (%) ..... O_2SAT
15. Oxyhemoglobin (HbO_2) (%) ..... HBO_2
16. FiO_2 (%) (see page 2 for O2 flow rate and FiO2 delivery) FIO2

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

Clinical Center Use Only
Date form entered (mm/dd/yyyy) __/__/ENTER_DT
Username of person entering this form ENTER_USER

PVDOMICS

PVDOMICS STUDY
Center Arterial Blood Gases (ABG) Form #207

Oxygen Delivery Equipment		
Device	**Flow Rate in Liters/minute**	**Percent FiO_2 delivered**
Nasal Cannula • Indicated for low-flow, low-percentage supplemental oxygen. • Flow rate of 1–6 L/min. • Delivers 25%–45% oxygen. • Pt can eat, drink, and talk. • Extended use can be very drying; use with a humidifier.	1	25%
	2	29%
	3	33%
	4	37%
	5	41%
	6	45%
Simple Face Mask • Indicated for higher percentage supplemental oxygen. • Flow rate of 6–10 L/min. • Delivers 35%–60% oxygen. • Lateral perforations permit exhaled CO_2 to escape. • Permits humidification.	6	35%
	7	41%
	8	47%
	9	53%
	10	60%
Nonrebreather Mask • Indicated for high percentage FiO_2. • Incorporates use of reservoir bag. • Flow rate of 10–15 L/min. • Delivers up to 100% oxygen. • One-way flaps prevent entrainment of room air during inspiration and retention of exhaled gases (namely CO_2) during expiration.	10–15	80%–100%*
	* Both flaps removed results in lower (80%–85%) FiO_2.	
	* One flap removed results in higher (85%–90%) FiO_2.	
	* Both flaps in place results in maximum (95%–100%) FiO_2.	
Venturi Mask (venti-mask) • Indicated for precise titration of percentage of oxygen. • Flow rate of 4–8 L/min. • Delivers 24%–60% oxygen. • Uses either a graduated dial set to desired FiO_2 or colored adapters selected to deliver desired FiO_2.	Blue	24%
	White	28%
	Orange	31%
	Yellow	35%
	Red	40%
	Green	60%

Revision of 01/20/2017

PVD_ECG_TRANS

Form #245
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Center Electrocardiogram (ECG)
Data Transmittal Form #245

Instructions: The ECG must be done specifically for the PVDOMICS Study. Form 245 is completed by the local technician or study coordinator and entered into the database once for each participant who consents to the PVDOMICS Study. Data will be reviewed by the Cardiovascular Physiology Core (CPC) at the DCC.

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of most recent ECG (mm/dd/yyyy)

4. Was a 12-lead ECG performed? (0=No, complete 4a; 1=Yes, skip to Q5) ..... ECG_PERFORM

   a. Primary reason ECG was not done ..... ECG_REASON
   1=Participant refused
   2=Participant has other medical condition that makes completing ECG difficult
   3=Equipment malfunction or lack of supplies
   Skip to Q200

5. ECG results status? (0=Normal (skip to Q7), 1=Abnormal) ..... RESULTS_STATUS

6. Are any circumstances in Q6a-c present that may explain an abnormal result? (0=No (skip to Q7), 1=Yes) ..... ABN_RESULT

   a. Extraneous movement/tremors? (0=No, 1=Yes) ..... TREMORS

   b. Extreme obesity? (0=No, 1=Yes) ..... EXTREME_OBESITY

   c. Medications causing bradycardia? (0=No, 1=Yes) ..... MEDS_BRADY
   (Medications may include but are not limited to: beta-blockers [propranolol, atenolol, metoprolol], verapamil, diltiazem, digoxin (toxicity), opiates [opium, morphine, and codeine])

7. Is the ECG technician name known (0=No, 1=Yes) ..... TECHNICIAN_KNOWN

   a. If yes, Username of ECG Technician who performed test ..... TECHNICIAN
   (Note: Username of ECG Tech is the first 6 letters of last name and first initial of first name)

8. Date PDF of rhythm strip transmitted to CPC? (mm/dd/yyyy) ..... __/__/TRANS_DT

200. Date form completed (mm/dd/yyyy) ..... __/__/COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __/__/ENTER_DT

Username of person entering this form ENTER_USER

Revision of 08/06/2018

PVD_ECG_RESULT

Form #246
Page 1 of 2

PVDOMICS

PVDOMICS STUDY
Clinical Physiology Core Electrocardiogram (ECG)
Core Results Form #246

Instructions: The ECG is read and this form is then completed by the Cardiovascular Physiology Core (CPC).

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of most recent ECG (mm/dd/yyyy)

4. ECG readability quality ECG_QUALITY
   (0=Unacceptable, skip to end of form, 1=Acceptable, continue, 2=Unacceptable, missing several key pieces of data) ..... ___
5. Heart Rate (bpm) ..... HR ..... ___ ___ ___
6. ECG rhythm (1=Normal (sinus) rhythm, skip to Q7, 2=Abnormal rhythm, complete Q6a-k) ..... ECG_RESULT
   a. Atrial fibrillation (0=No, 1=Yes) ..... ATRIAL_FIB ___
   b. Atrial flutter (0=No, 1=Yes) ..... ATRIAL_FLUTTER
   c. Sinus arrhythmia (0=No, 1=Yes) ..... SINUS_ARRHY
   d. Sinus bradycardia (0=No, 1=Yes) ..... SINUS_BRADY
   e. Supraventricular tachycardia (0=No, 1=Yes) ..... SUPRA_TACHY
   f. Sinus tachycardia (0=No, 1=Yes) ..... SINUS_TACHY
   g. Ventricular tachycardia (0=No, 1=Yes) ..... VENT_TACHY ___
   h. Wide complex tachycardia (0=No, 1=Yes) ..... COMPLEX_TACHY
   i. Junctional rhythm (0=No, 1=Yes) ..... JUNCT_RHYTHM
   j. A paced (0=No, 1=Yes) ..... A_PACED ___
   k. V paced (0=No, 1=Yes) ..... V_PACED ___
   l. AV paced (0=No, 1=Yes) ..... AV_PACED ___
7. ECG heart block results
   (0=No heart block, skip to Q8, 1=Heart block present, complete Q7a-g, 9 = Unknown) ..... ECG_HB_RESULT
   a. First degree AV block (0=No, 1=Yes) ..... FIRST_AV_BLOCK
   b. Second degree AV block (type I) (0=No, 1=Yes) ..... SEC_AV_BLOCK_TYP1
   c. Second degree AV block (type II) (0=No, 1=Yes) ..... SEC_AV_BLOCK_TYP2
   d. Third degree (complete) AV block (0=No, 1=Yes) ..... THIRD_AV_BLOCK
   e. Right bundle branch block (0=No, 1=Yes)) ..... RT_BUNDLE_BLOCK
   f. Left bundle branch block (0=No, 1=Yes) ..... LT_BUNDLE_BLOCK
   g. Intraventricular conduction delay (IVCD) (0=No, 1=Yes) ..... IVCD ___

8. Chamber enlargement
(1=Normal morphology, skip to Q9, 2=Abnormal, complete Q8a-f, 9 = Unknown) ..... CHAMBER_ENLARGE
   a. Right ventricular hypertrophy (0=No, 1=Yes) ..... RT_VENT_HYPER
   b. Right atrial enlargement (0=No, 1=Yes) ..... RT_ARTIAL_ENLARGE
   c. Other right atrial abnormality (0=No, 1=Yes) ..... OTH_RT_ATRIAL_ABN
   d. Left ventricular hypertrophy (0=No, 1=Yes) ..... LT_VENT_HYPER
   e. Left atrial enlargement (0=No, 1=Yes) ..... LT_ATRIAL_ENLARGE
   f. Other left atrial abnormality (0=No, 1=Yes)) ..... OTH_LT_ATRIAL_ABN
9. PR interval (milliseconds) ..... PR_INTERVAL ___
10. QTc interval (milliseconds) ..... QTC_INTERVAL ___
11. QRS duration (milliseconds) ..... QRS_DURATION ___
12. QRS Axis (degrees) (*if appropriate, record '-' before degrees)* ..... QRS_AXIS ___
13. Q waves present? (0=No, 1=Yes, complete 13a-j, 9 = Unknown) ..... Q_WAVES ___
   a. Anterolateral, age recent or probably acute (0=No, 1=Yes) ANT_LAT_RECENT_ACUTE
   b. Anterolateral, age indeterminate or probably old (0=No, 1=Yes) ANT_LAT_INDETER_OLD
   c. Anterior or anteroseptal, age recent or probably acute (0=No, 1=Yes) ANTERIOR_RECENT_ACUTE
   d. Anterior or anteroseptal, age indeterminate or probably old (0=No, 1=Yes) ANTERIOR_INDETER_OLD
   e. Lateral, age recent or probably acute (0=No, 1=Yes) ..... LAT_RECENT_ACUTE
   f. Lateral, age indeterminate or probably old (0=No, 1=Yes) ..... LAT_INDETER_OLD
   g. Inferior, age recent or probably acute (0=No, 1=Yes) ..... INFERIOR_RECENT_ACUTE
   h. Inferior, age indeterminate or probably old (0=No, 1=Yes) INFERIOR_INDETER_OLD
   i. Posterior, age recent or probably acute (0=No, 1=Yes) ..... POST_RECENT_ACUTE
   j. Posterior, age indeterminate or probably old (0=No, 1=Yes) POST_INDETER_OLD
14. ST segment abnormalities? (No=0, Yes=1, complete 14a-d, 9 = Unknown) ST_SEGMENT_ABN
   a. Nonspecific ST and/or T wave abnormalities (0=No, 1=Yes) ..... NONSPEC_WAVE_ABN
   b. ST and/or T wave abnormalities suggesting myocardial ischemia (0=No, 1=Yes) WAVE_ABN_ISCH
   c. ST and/or T wave abnormalities suggesting myocardial injury (0=No, 1=Yes) WAVE_ABN_INJURY
   d. Prolonged QT interval (0=No, 1=Yes) ..... PROLONG_QT ___
15. Username of physician reading the ECG and filling out this form ..... PHYS_USERNAME
(*Username of person is the first 6 letters of last name and first initial.)*
200. Date form completed (mm/dd/yyyy) ..... __/__/ COMP_DT
201. Username of person completing/reviewing completeness of this form ..... COMP_USER

CPC CoreUse Only

Date Form Entered (mm/dd/yyyy) ___/___/ ENTER_DT

Username of person entering this form ENTER_USER

PVD_ECHO_TRANS

PVDOMICS

PVDOMICS Study
Echocardiogram (ECHO) Transmittal Form #250

Instructions: This form is used for both uploading data to AG Mednet for the Imaging Core Lab (ICL) and PVDOMICS database. *(Note that Q3b and 7a-b will not appear on AG Mednet screen.)* Review MOP Chapter 60 prior to testing.

Study Coordinator Completes Questions 1-5.

PID | AC | VISIT_DT

1. Identification Number — 2. Alphacode — 3a. Date of ECHO (mm/dd/yyyy)

3. b. Was an ECHO done? ..... ECHO_DONE

1=Yes, ECHO completed per PVDOMICS study protocol

The following responses are considered PVDOMICS Study DEVIATIONS

2=Yes, ECHO done but did not use PVDOMICS ECHO protocol (*missing bubble study and/or other study variables)*, logistically had a clinical ECHO study

3=No, attempted but participant could not tolerate procedure *(skip to end of form)*

4=No, scheduling issue *(skip to end of form)*

5=No, other logistical issue at the site *(skip to end of form)*

6=No, participant refused even after study PI talked with participant *(skip to end of form)*

4. Gender (1=Male, 2=Female) (*database will auto populate from Form100*) ....

5. Visit Type (1=Qualification, 2=Baseline, 3=Follow-up) ..... VIST .....

(Note: Use '1=Qualification' for new ECHO sonographer submission. Use '2=Baseline' for a participant's study submission. Disregard response 3 for now.)

Sonographer Completes Questions 6-12.

6. a. Was blood pressure measured at the beginning of ECHO ..... BP_MEAS

0=No, BP measures not collected, 1=Yes

b. If yes, blood pressure measures (mmHg) (systolic/diastolic) ..... BP_SYS / BP_DIA

7. Agitated saline contrast *(aka bubble study)* (*for study identified in Q3a)* (0=No, 1=Yes) ..... ~~AGITAT~~ SALINE

a. If Q7=0-No, why not? ..... AGITAT_NOT_RSN

1=Historical study done
2=No IV access
3=Pt. refused
4=Logistics
5=Known intracardiac shunt

a.1. If Q7a=1, date of previous contrast exam (mm/dd/yyyy)___ ___/___ PREV_EXAM_DT

a.2 What was exam conclusion? (0=Negative, 1=Positive) ..... EXAM_CONCL

a.3. If Q7a2=1-Positive, was it? ..... POS_DTL

(1=Right to left, 2=Left to right, 3=Not determined, 4=Bidirectional, 9=Unknown)

Add comments on next page.

02/27/2019: Q7a3 response code of 4=Bidirectional added. Revision date updated.

8. a. Contrast enhancement for left ventricular opacification (LVO) ..... CONTRAST
   0=No, contrast agent not collected, 1=Yes

   b. If yes, name of contrast agent used ..... CONTRAST_USED
   1=Optison
   2=Definity
   3=Lumason
   8=Other, specify_____

   c. Total contrast volume (mL) ..... CONTRAST_VOL

Comments_____

_____

_____

9. a. Username of PVDOMICS-trained ECHO Sonographer responsible for echocardiogram ..... SONOGRAPHER
   (*PVDOMICS-trained sonographer should have Form 10-Study Personnel entered in the PVDOMICs database in order for username to appear in the drop down box)*

   b. Name of ECHO Sonographer who performed ECHO *(will not be entered into PVDOMICS database):* _____

Ultrasound Equipment Used for this ECHO

10. Ultrasound manufacturer name ..... MANUFACTURER
11. Model # ..... MODEL_NO
12. Serial # ..... SERIAL_NO

Transmission Details for ECHO to AG Mednet – ***Coordinator completes Q13 through end of form.***

13. Method of transmission (1=Digital transfer, 8=Other, specify_____) ..... TRANS_METHOD
14. Date ECHO file transmitted (mm/dd/yyyy) ..... TRANS_DT
    (Date file transmitted must be greater or equal to the date the form is completed.)

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

Clinical Center Use Only
Date form entered (mm/dd/yyyy) __/__/ ENTER_DT
Username of person entering this form ENTER_USER

02/27/2019: Q7a3 response code of 4=Bidirectional added. Revision date updated.

PVDOMICS Study
Cardiac MRI Transmittal Form #251

Instructions: This form is used for both uploading data to AG Mednet for the Imaging Core Lab (ICL) and uploading data to the DCC database. Review MOP Chapter 70 prior to testing.

Study Coordinator Completes Questions 1-5. AC VISIT_DT

PD [ ][ ][ ][ ][ ][ ] – [ ][ ] [ ][ ][ ][ ][ ][ ][ ][ ]

1. Identification Number 2. Alphacode 3a. Date of Cardiac MRI (mm/dd/yyyy)

3. b. Was a cardiac MRI done? ..... MRI_DONE

1=Yes, MRI completed per PVDOMICS study protocol
2=Yes, MRI done but did not use PVDOMICS MRI protocol (missing study variables), logistically had a clinical MRI
3= Yes, MRI done but had non-contrast MRI due to Gadolinium allergy
4=No, excluded from MRI per MOP Chapter 70.8 medical contraindications
5=No, excluded from MRI due to other medical contraindication not listed in MOP 70.8/safety issue
6=No, attempted but participant could not tolerate procedure
7=No, scheduling issue
8=No, neither insurance nor research funds cover MRI
9=No, other logistical issue at the site
10=No, logistical issue with participant (could not fit into the scanner, unable to hold breath)
11=No, participant refused even after study PI talked with participant

4. Gender (1=Male, 2=Female) (*database will autopopulate from Form100*)..... [ ]

5. Visit Type ..... VIST ....
1=Qualification, 2=Baseline, 3=Follow-up

MRI Technologist Completes Questions 6-20.

6. a. Blood pressure measured at the beginning of cardiac MRI? ..... BP_MEAS
0=No, BP measures not collected, 1=Yes

b. If yes, blood pressure measures (mmHg) (systolic/diastolic) ..... BP_SYS / BP_DIA

7. a. Was there a cardiac rhythm disturbance during MRI? (0=No, 1=Yes)..... DISTURB ....

b. If yes, what type of rhythm disturbance? ..... DISTURB_TYPE
1=Atrial fibrillation
2=Bradycardia
8=Other, specify _____

8. a. Was average heart rate collected during MRI? (0=No, 1=Yes)..... HR_COLLECTED

b. If yes, average heart rate during MRI (bpm) ..... HR ....

9. a. Was contrast agent used? ..... CONTRAST_USED
0=No contrast agent used
1=Ablabar (gadofoveset trisodium)
2=Magnevist (gadopentetate dimeglumine)
3=MultiHance (gadopentetate dimeglumine)
4=OptiMARK (gadoversetamide)
5=Dotarem (gadoterate meglumine)
6=Omniscan (gadodiamide)
7=ProHance (gadoteridol)
8=Other, specify _____

b. Total contrast volume (mL)..... CONTRAST_VOL

10. MRI start time (24-hr clock) (hh:mm) ..... MRI_START_:TM
11. Injection start time (24-hr clock) (hh:mm) ..... INJ_START_TM:_ _
12. Look-Locker sequence start time (24-hr clock) (hh:mm) ..... LL_START_TM:_ _
13. Delayed enhancement sequence start time (24-hr clock) (hh:mm) ..... DELAY_START_TM
14. MOLLI sequence start time (24-hr clock) (hh:mm), if performed ..... MOLLI_START_TM
15. MRI end time (24-hr clock) (hh:mm) ..... MRI_END_:TM

Comments _____

_____

16. Is the MRI Tech name known (0=No, 1=Yes) ..... TECH_KNOWN
    a. If yes, username of MRI Tech who performed cardiac MRI ..... _ _ MRI_TECH
    b. Name of MRI Tech who performed cardiac MRI *(will not be entered into the database)*

    _____

Imaging Equipment Used for this Cardiac MRI

17. MRI manufacturer ..... MANUFACTURER
    1=GE 3=Siemens
    2=Philips 8=Other, specify _____
18. Model # ..... _____ MODEL_NO
19. Serial Number # ..... _ _ _ SERIAL_NO
20. Field Strength: Tesla (1=1.5 T, 2=3.0 T) ..... FIELD_STRENGTH

Transmission Details for Cardiac MRI to AG Mednet- ***Coordinator completes Q21 through end of form.***

21. Method of transmission (1=Digital transfer, 8=Other, specify _____ TRANS_METHOD
22. Date MRI file transmitted to AG Mednet (mm/dd/yyyy) ..... TRANS_DT
    (Date file transmitted must be greater or equal to the date the form is completed.)

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

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT
Username of person entering this form ENTER_USER

PVD_CT_TRANS

PVDOMICS

PVDOMICS STUDY
Center Chest CT Scan and Report
Transmittal Form #252

Instructions: This chest CT scan form is completed once for each PVDOMICS participant by center personnel. Enter this form as soon as possible after the CT scan is performed. An email notification will be sent by the database to the Lung Imaging Core **(LIC)** to expect transmitted data for this participant. *Note: Date of chest CT scan must be on or after date of enrollment. Use Form 253 to capture data from a historical CT scan.*

PID [ ][ ][ ][ ][ ][ ] AC [ ][ ] VISIT_DT [ ][ ][ ][ ][ ][ ][ ][ ]

1. Identification Number 2. Alphacode 3. Date of chest CT (mm/dd/yyyy)

4. Was the chest CT done? ..... CT_PERFORM ___

1=Yes, scan completed
2=No, logistics problem related to the participant
3=No, participant was too claustrophobic
4=No, participant was too large to fit into machine
(If CT scan *was not done, skip to Q200.)*
5=No, medical contraindication/safety issue detected
6=No, logistic problem related to the PVDOMICs clinical site (e.g., staffing, scheduling)
7=No, logistic problem related to local CT facility
8=No, participant refused

5. Type of scan ..... CT_SCAN_TYPE

1=Chest CT without contrast (Non-contrast Chest CT)
2=Chest CT with contrast (Routine post contrast CT)
3=Chest CT with angiogram (Chest CTA PE protocol) ***Note: If scan is obtained, do not proceed with V/Q scan.***

6. Was this CT scan completed for research only? ..... RESEARCH ___

0=No, scan used for clinical purposes
1=Yes, research only

(Q7 Equipment number removed)

8. Is final report from local radiologist available, de-identified and attached? (0=No, 1=Yes).... FINAL_REP

9. Is the CT Tech name known (0=No, 1=Yes) ..... TECH_KNOWN

   a. If yes, Username of CT Tech who performed test ..... TECHNOLOGIST
   (Note: Username of CT Tech is the first 6 letters of last name and first initial of first name)

   b. Name of CT Tech who performed scan *(will not be entered into the database)* _____

10. a. Date de-identified images transmitted to LIC (mm/dd/yyyy)..... __ __ / __ __ / TRANS_DT

    b. Date de-identified report transmitted to LIC (mm/dd/yyyy) ..... __ __ / REP_TRANS_DT

11. Type of image format file transmitted to LIC ..... FILE_TYPE

1=DICOM, 2=Other format

For DCC Use Only:
198. CT scan unreadable per LIC? ..... UNREADABLE ___
199. Date DCC notified ..... NOTIFY_DT / _ _ _ _

200. Date this form completed (mm/dd/yyyy) ..... __ __ / __ __ / COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER ___

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __ / __ __ / ENTER_DT

Username of person entering this form ENTER_USER

Revision of 07/05/2017

PVD_CT_TRANS_HIST

Form #253
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Center Historical Chest CT Scan
Data Transmittal Form #253

Instructions: This form is completed only if a historical chest CT scan is submitted. The scan results should have been completed within 1 year of enrollment into the PVDOMICS study. An email notification will be sent by the database to the Lung Imaging Core **(LIC)** to expect transmitted data for this participant.

Do not complete this form if a current chest CT scan will be completed for the PVDOMICS study.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date of historical CT (mm/dd/yyyy)

4. Type of scan ..... CT_SCAN_TYPE
   1=Chest CT without contrast (Non-contrast Chest CT)
   2=Chest CT with contrast (Routine post-contrast CT)
   3=Chest CT with angiogram (Chest CTA PE protocol)

5. Is a final report from local radiologist de-identified and attached? (0=No, 1=Yes) ..... FINAL_REP

6. Is the CT Tech name known (0=No, 1=Yes) ..... TECH_KNOWN
   a. If yes, Username of CT Tech who performed test ..... TECHNOLOGIST
      (Note: Username of CT Tech is the first 6 letters of last name and first initial of first name)

7. Date de-identified images transmitted to LIC (mm/dd/yyyy) ..... __ __ / TRANS_DT
8. Date de-identified report transmitted to LIC (mm/dd/yyyy) ..... REP_TRANS_DT
9. Type of image format file transmitted to LIC (1=DICOM, 2=Other format) ..... FILE_TYPE

For DCC Use Only:
198. CT scan unreadable per LIC? (0=No, 1=Yes) ..... UNREADABLE
199. Date DCC notified ..... NOTIFY_DT

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

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __ / __ __ / ENTER_DT
Username of person entering this form ENTER_USER

PVD_VQSCAN_TRANS

PVDOMICS

PVDOMICS STUDY
Clinical Center Ventilation/Perfusion (V/Q) Scan Report Form #254

Instructions: All patients are required to have a ventilation-perfusion lung scan for detection of possible pulmonary emboli*. V/Q scans performed within 4 years prior to enrollment can be used provided acceptable results are made available to the DCC and there has been no change in clinical status of the participant.

*A V/Q scan is not required if the participant has known parenchymal lung disease or has had a positive CT angiogram in the past year for which the results (DICOM images) and final report are provided to the DCC Lung Imaging Core. If the CTA is non-diagnostic or negative, then a V/Q scan is required.

As of 06/14/2018, the clinical center physician should review the local radiologist's final report to interpret the probability of a pulmonary embolus. Radiopharmaceutical agents should be documented on this first, if available on the report. ***(The V/Q scan report no longer needs to be transmitted to the DCC but should be retained in the participant's study binder as source documentation.)***

PID | AC | VISIT_DT

1. Identification Number
2. Alphacode
3. Date of V/Q scan (mm/dd/yyyy)

4. Was a lung ventilation/perfusion (V/Q) scan performed for the PVDOMICS Study? SCAN_PERF
   1=Yes, scan completed for PVDOMICS Study *(all questions must answered)*
   2=No, V/Q scan not done because a Chest CTA PE protocol was done. Results and DICOM images available. *(skip to Q200)*
   3=No, logistics problem *(skip to Q200)*
   4=No, medical contraindication/safety issue detected *(skip to Q200)*
   5=No, historical scan used *(all questions must answered)*
   6=No, participant refused *(skip to Q200)*
   7=No, participant has parenchymal lung disease

Clinical Center Interpretation of Lung Scan Results

PULM_EMBOLISM

5. What was the nuclear medicine report reading on the probability of a pulmonary embolism?..... ___
   0=None 2=Low 4=High 6=No evidence of pulmonary embolism
   1=Very low 3=Intermediate 5=Uninterpretable

Radiopharmaceutical Materials Used

6. Was a radiopharmaceutical agent for **Ventilation scan** identified on local report (0=No, 1=Yes) VENT_AGENT

   If yes, complete Q6a-b:

   a. Type of radiopharmaceutical agent administered ..... VENT_TYPE
      1=Aerosol (99mTc-DTPA)
      2=Xenon (133Xe) gas
      9=Unspecified

   b. Activity (mCi) ..... VENT_ACTIVITY

*6/14/2018- Q6 & 7-radiopharmaceutical agents added. Dropped transmission of V/Q report to DCC via secure portal. Added Q197-physician review of form; *not obtained retrospectively. Q198 & Q199 removed. V/Q Core Form 256 dropped. 7/5/2018, Q6 & 7: a code of 9=Unspecified was added. Q7 reworded for consistency with Q6. Q4 added: 7=No, participant has parenchymal lung disease. 7/9/18: Q6b & Q7b format width increased to 2 digits.*

7. Was a radiopharmaceutical agent for **Perfusion scan** identified on the local report (0=No, 1=Yes) ..... PERF_AGENT

   If yes, complete Q7a - b:

   a. Type of radiopharmaceutical agent administered ..... PERF_TYPE
      1=99mTc-MAA
      9=Unspecified
      (Contact the DCC if other radiopharmaceutical agent is named and it can be added)

   b. 99mTc-MAA activity (mCi)..... PERF_ACTIVITY

8. Any comments? (0=No comments, 1=Yes, specify below)..... COMMENTS_YN

Comments *(entered into database)*: COMMENTS

197. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form* ..... PHYS_REVIEWER
(Username of physician is the first 6 letters of last name and first initial.)

200. Date form completed (mm/dd/yyyy)..... __/__/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __/__/ ENTER_DT

Username of person entering this form ENTER_USER

*6/14/2018- Q6 & 7-radiopharmaceutical agents added. Dropped transmission of V/Q report to DCC via secure portal. Added Q197-physician review of form; *not obtained retrospectively. Q198 & Q199 removed. V/Q Core Form 256 dropped. 7/5/2018, Q6 & 7: a code of 9=Unspecified was added. Q7 reworded for consistency with Q6. Q4 added: 7=No, participant has parenchymal lung disease. 7/9/18: Q6b & Q7b format width increased to 2 digits.*

ECHO Variables

	Variable Name	Description	Unit	Format	Codes	Comments
1	PID	Patient ID	na	NUM (6)		site(2) subject(4) Ex. 123456
2	AC	Alphacode	-	CHAR (2)		alpha(2) Ex. AB
3	VISIT	Visit Name	na	CHAR (15)	QUALIFICATION BASELINE FOLLOW UP 1 UNSCHEDULED	-
4	VISIT_DT	Visit Date	-	CHAR (15)		DD MON YYYY
5	AAMD	Mid Ascending Aorta Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
6	AOSD	Aortic Sinus Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
7	STJD	Sinotubular Junction Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
8	AVEOA	AoV EOA Area	cm2	NUM (6.2)		NA – NM – ND may appear for blank values
9	LVET	LV Ejection Time	ms	NUM (6.2)		NA – NM – ND may appear for blank values
10	AVMG	AoV Mean Gradient	ms	NUM (6.2)		NA – NM – ND may appear for blank values
11	AVPG	AoV Peak Gradient	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values
12	AVPV	AoV Peak Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
13	AVVTI	AoV TVI	cm	NUM (6.2)		NA – NM – ND may appear for blank values
14	ASDL	Atrial Septal Defect Location	na	CHAR (40)	None Primum Secundum Sinus Venosus NM ND	MULTIPLE locations possible. Semicolon (;) delimiter separates locations.
15	CTHRBL1	Chamber Thrombus Location (core)	-	CHAR (30)	None LA LV RA RV PA IVC NM ND	MULTIPLE locations possible. Semicolon (;) delimiter separates locations.
16	CMT	Comments	-	CHAR (200)		-
17	MVEELAT1	E / e' Lateral	-	NUM (6.2)		NA – NM – ND may appear for blank values
18	MVEEMED1	E / e' Septal	-	NUM (6.2)		NA – NM – ND may appear for blank values
19	LVGLOB	LV Global Peak Long Strain	%	NUM (6.2)		NA – NM – ND may appear for blank values
20	RVGLOB3	Global RV Free Wall Peak Long Strain (3 Segments)	%	NUM (6.2)		NA – NM – ND may appear for blank values
21	RVGLOB6	Global RV Free Wall Peak Long Strain (6 Segments)	%	NUM (6.2)		NA – NM – ND may appear for blank values
22	HVAR	Hepatic Vein Peak Atrial Reversal	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
23	HVD	Hepatic Vein Peak D Wave	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
24	HVS	Hepatic Vein Peak S Wave Peak	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
25	HR	Heart Rate	bpm	NUM (6.2)		NA – NM – ND may appear for blank values

26	IVSD	Intraventricular Septum Diastolic	cm	NUM (6.2)		NA – NM – ND may appear for blank values
27	LAA	Left Atrial Area	cm2	NUM (6.2)		NA – NM – ND may appear for blank values
28	LAV4C	Left Atrial Volume 4 CH	mL	NUM (6.2)		NA – NM – ND may appear for blank values
29	LAVIX	Left Atrial Volume Index	mL/m2	NUM (6.2)		NA – NM – ND may appear for blank values
30	LVCOBPC	Contrast LV Cardiac Output	L/mln	NUM (6.2)		NA – NM – ND may appear for blank values
31	LVCOBP	LV Cardiac Output	L/min	NUM (6.2)		NA – NM – ND may appear for blank values
32	LVEDD	LV End Diastolic Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
33	LVDF	LV Diastolic Function	-	CHAR (15)	Normal Stage 1 Stage 2 Stage 3 NM ND	-
34	LVEF	LV Visual Ejection Fraction	%	NUM (6.2)		NA – NM – ND may appear for blank values
35	LVEFA4C	LV EF 4CH	%	NUM (6.2)		NA – NM – ND may appear for blank values
36	LVEFA4CC	C4C LV Ejection Fraction	%	NUM (6.2)		NA – NM – ND may appear for blank values
37	LVEFBP	BP LV Ejection Fraction	%	NUM (6.2)		NA – NM – ND may appear for blank values
38	LVEFBPC	Contrast BP LV Ejection Fraction	%	NUM (6.2)		NA – NM – ND may appear for blank values
39	LVMASSC	LV Mass Corr	g	NUM (6.2)		NA – NM – ND may appear for blank values
40	LVTEI	LV TEI Index	-	NUM (6.2)		NA – NM – ND may appear for blank values
41	LVESD	LV End Systolic Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
42	LVSVBP	LV Stroke Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
43	LVSVBPC	Contrast LV Stroke Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
44	LVEDVA4C	LVEDV 4 CH	mL	NUM (6.2)		NA – NM – ND may appear for blank values
45	LVDVA4CC	C4CLV End Diastolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
46	LVEDVBP	BP LV End Diastolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
47	LVEDVBPC	Contrast BP LV End Diastolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
48	LVESVA4C	LVESV 4CH	mL	NUM (6.2)		NA – NM – ND may appear for blank values
49	LVSVA4CC	C4CLV End Systolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
51	LVESVBP	BP LV End Systolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
52	LVESVBPC	Contrast BP LV End Systolic Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
53	LVOTD	LVOT Diameter	cm	NUM (6.2)		NA – NM – ND may appear for blank values
54	LVOTVTI	LVOT TVI	cm	NUM (6.2)		NA – NM – ND may appear for blank values
55	LVPWD	Left Ventricular Posterior Wall Diastolic	cm	NUM (6.2)		NA – NM – ND may appear for blank values

56	MRG	Mitral Valve Regurgitation Degree	-	CHAR (10)	None Trace Mild Moderate Severe NM ND	-
57	MVA	Mitral Valve A Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
58	MVACD	Mitral Annular Calcification Severity	-	CHAR (10)	Mild Moderate Severe NM ND	-
59	MVDT	Mitral Valve Deceleration Time	ms	NUM (6.2)		NA – NM – ND may appear for blank values
60	MVE	Mitral Valve E Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
61	MVELAT	MV Lateral e'	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
62	MVESEP	MV Septal e'	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
63	PFO2	Patent Foramen Ovale Present	-	CHAR (10)	Yes No NM ND	-
65	PEFFL1	Pericardial Effusion Location	-	CHAR (22)	None LV RV RA LA NM ND	MULTIPLE locations possible. Semicolon (;) delimiter separates locations.
66	PEFFS1	Pericardial Effusion Severity	-	CHAR (8)	None Trivial Mild Moderate Severe NM ND	-
67	PRLDV	Peak Pulmonic Regurgitation Late Diastolic Flow	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
68	PREDV	Peak Pulmonic Regurgitation Early Diastolic Flow	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
69	PR	Pulmonic Regurgitation	-	CHAR (10)	None Trace Mild Moderate Severe NM ND	-
70	PVADUR	A Duration	ms	NUM (6.2)		NA – NM – ND may appear for blank values
71	QPQS1	Shunt Ratio	-	NUM (6.2)		NA – NM – ND may appear for blank values
72	RAP	Right Atrial Pressure	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values
73	RADMAJ	Right Atrial Dimension, Major	cm	NUM (6.2)		NA – NM – ND may appear for blank values
74	RADMIN	Right Atrial Dimension, Minor	cm	NUM (6.2)		NA – NM – ND may appear for blank values
75	RAV	Right Atrial Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
76	RAVIX	RA Volume Index	mL/m2	NUM (6.2)		NA – NM – ND may appear for blank values
77	RUPVA	Pulmonary Vein Atrial Reversal Peak	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values

78	RUPVD	Pulmonary Vein D Wave Peak	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
79	RUPVS	Pulmonary Vein S Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
80	RVAD	RV End Diastolic Area	cm^2	NUM (6.2)		NA – NM – ND may appear for blank values
81	RVADC	Contrast RV End Diastolic Area	cm^2	NUM (6.2)		NA – NM – ND may appear for blank values
82	RVAS	RV End Systolic Area	cm^2	NUM (6.2)		NA – NM – ND may appear for blank values
83	RVASC0	Contrast RV End Systolic Area	cm^2	NUM (6.2)		NA – NM – ND may appear for blank values
84	RVEF3D	3D RVEF	%	NUM (6.2)		NA – NM – ND may appear for blank values
85	RVFAC	RV Fractional Shortening	%	NUM (6.2)		NA – NM – ND may appear for blank values
86	RVFACC1	Contrast RV Fractional Shortening	%	NUM (6.2)		NA – NM – ND may appear for blank values
87	RVMIND	RV End Diastolic Basal Dimension	cm	NUM (6.2)		NA – NM – ND may appear for blank values
88	RVMINS	RV End Systolic Dimension (base)	cm	NUM (6.2)		NA – NM – ND may appear for blank values
89	RVSIZE	Right Ventricle Size (visual)	-	CHAR (25)	Normal Mildly Dilated Moderately Dilated Severely Dilated NM ND	-
90	RVFUNC	Right Ventricle Function (visual)	-	CHAR (25)	Normal Mild Decrease Moderate Decrease Severe Decrease NM ND	-
91	RVTEI	RV TEI Index (RVET and TV C-O, calculation)	-	NUM (6.2)		NA – NM – ND may appear for blank values
92	RVTITDI1	RV TEI Index from TDI (Pulsed wave TV annular lateral wall TDI, calculation)	-	NUM (6.2)		NA – NM – ND may appear for blank values
93	RVEDV3D	3D RVED Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
94	RVESV3D	3D RVES Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
95	RVWD	RVD Wall Thickness	cm	NUM (6.2)		NA – NM – ND may appear for blank values
96	RVOTET	RV Ejection Time	ms	NUM (6.2)		NA – NM – ND may appear for blank values
97	RVOTDDST	RVOT Diameter PSAX View - (valve level) in Diastole Distal	cm	NUM (6.2)		NA – NM – ND may appear for blank values
98	RVOTVTI	RVOT Velocity Time Integral	cm	NUM (6.2)		NA – NM – ND may appear for blank values
99	RVSPSAL	RVSP Saline	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values
100	RVSP	Right Ventricular Systolic Pressure	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values
101	TAPSE	Tricuspid Annular Plane Systolic Excursion	cm	NUM (6.2)		NA – NM – ND may appear for blank values
102	TAR	Aortic Regurgitation Degree	-	CHAR (10)	None Trace Mild Moderate Severe NM ND	-
103	TRPVSAL	TR Vmax Saline	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values

104	TRPV	Tricuspid Valve Peak Regurgitation Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
105	TVDT	Tricuspid Valve Deceleration Time	ms	NUM (6.2)		NA – NM – ND may appear for blank values
106	TVEFW	TV Lateral e'	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
107	TVEE	TV E/e'	ms	NUM (6.2)		NA – NM – ND may appear for blank values
108	TVE	Tricuspid Valve E Velocity	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
109	TRG	Tricuspid Valve Regurgitation Degree	-	CHAR (10)	None Trace Mild Moderate Severe NM ND	-
110	TVSFW	TV Lateral s'	cm/s	NUM (6.2)		NA – NM – ND may appear for blank values
111	VSDL	Ventricular Septal Defect Location	-	CHAR (46)	None Perimembranous Muscular Supracristal NM ND	MULTIPLE locations possible. Semicolon (;) delimiter separates locations.
112	IASSF2	Shunt Flow Direction	-	CHAR (20)	None Left to right Right to left Bidirectional Intrapulmonary NM ND	-
113	LVEDV3D	3D LVED Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
114	RVOTDPRX	RVOT Diameter PSAX View – (proximal level) in Diastole Proximal	cm	NUM (6.2)		NA – NM – ND may appear for blank values
115	LVEF3D	3D LVEF	%	NUM (6.2)		NA – NM – ND may appear for blank values
116	RVDF	RV Diastolic Function	-	CHAR (10)	Normal Stage 1 Stage 2 Stage 3 NM ND	-
117	LVESV3D	3D LVES Volume	mL	NUM (6.2)		NA – NM – ND may appear for blank values
118	PAEDG	PA End Diastolic Pressure Gradient	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values
119	PAMDG	PA Mean Pressure	mmHg	NUM (6.2)		NA – NM – ND may appear for blank values

Missing Data Codes for numeric fields –

NA, NM, ND as the missing data codes for numeric fields. When a numeric value cannot be provided for a numeric field, instead of a number, one of these codes will be output to the transfer file.

NA = Not Applicable NM= Not Measurable ND= Not Recorded by Site

Default precision for numeric fields –

Two decimal digits.

Non-numeric fields defined with code lists –

Per sponsor request, the selected text string as shown in above definition table (code column) will be output to the transfer file.

List of MRI Variables

	Variable Name	Description	Unit	Format	Codes	Comments
1	PID	Patient ID	na	NUM (6)		site(2) subject(4) EX. 123456
2	AC	Alphanumeric	na	CHAR (2)		alpha(2) Ex. A1
3	VISIT_DT	Visit Date	na	CHAR (11)		DD MON YYYY
4	VISIT	Visit Name	na	CHAR (9)	Baseline Follow-up	
5	BPS	Blood Pressure Systolic	mmHg	NUM (3)		
6	BPD	Blood Pressure Diastolic	mmHg	NUM (3)		
7	LVEDV	Left Ventricular End Diastolic Volume	ml	NUM (6.2)		
8	LVESV	Left Ventricular End Systolic Volume	ml	NUM (6.2)		
9	LVSV	Left Ventricular Stroke Volume	ml	NUM (6.2)		
10	LVEF	Left Ventricular Ejection Fraction	%	NUM (6.2)		
11	LVCO	Left Ventricular Cardiac Output	l/min	NUM (6.2)		
12	LVMASS	Left Ventricular Mass	g	NUM (6.2)		
13	LAEDV	Left Atrial End Diastolic Volume	ml	NUM (6.2)		
14	LAESV	Left Atrial End Systolic Volume	ml	NUM (6.2)		
15	RVEDV	Right Ventricular End Diastolic Volume	ml	NUM (6.2)		
16	RVESV	Right Ventricular End Systolic Volume	ml	NUM (6.2)		
17	RVSV	Right Ventricular Stroke Volume	ml	NUM (6.2)		
18	RVEF	Right Ventricular Ejection Fraction	%	NUM (6.2)		
19	RVCO	Right Ventricular Cardiac Output	l/min	NUM (6.2)		
20	RVMASS	RV Mass	g	NUM (6.2)		
21	RAEDV	Right Atrial End Diastolic Volume	ml	NUM (6.2)		
22	RAESV	Right Atrial End Systolic Volume	ml	NUM (6.2)		
23	LGEM	Late Gd Enh. Mass	g	NUM (6.2)		
24	LELVM	Late Enh. / LV mass	%	NUM (6.2)		
25	QFLATFF	Q Flow Aorta Total Forward Flow	ml	NUM (6.2)		
26	AVRF	AV Regurgitant Fraction 1	%	NUM (6.2)		
27	QFLAF	Q Flow Aorta Forward	ml	NUM (6.2)		
28	QFLAB	Q Flow Aorta Backward	ml	NUM (6.2)		
29	QFLMPATFF	Q Flow MPA Total Forward Flow	ml	NUM (6.2)		
30	PVRF	PV Regurgitant Fraction 2	%	NUM (6.2)		
31	QFLMPAF	Q Flow MPA Forward	ml	NUM (6.2)		
32	QFLMPAB	Q Flow MPA Backward	ml	NUM (6.2)		

33	QFLRPATFF	Q Flow RPA Total Forward Flow	ml	NUM (6.2)		
34	QFLPATFF	Q Flow LPA Total Forward Flow	ml	NUM (6.2)		
35	QPQS	Pulmonary Flow/Systemic Flow	unitless	NUM (6.2)		
36	LVPGLSS	Left Ventricular Peak Global Longitudinal Systolic Strain	%	NUM (6.2)		
37	RVPGLSS	Right Ventricular Peak Global Longitudinal Systolic Strain	%	NUM (6.2)		
38	LALVPGLSS	Long Axis Left Ventricular Peak Global Longitudinal Systolic Strain	%	NUM (6.2)		
39	MVRV	Mitral Valve Regurgitant Volume	ml	NUM (6.2)		
40	MVRF	Mitral Valve Regurgitant Fraction	%	NUM (6.2)		
41	TVRV	Tricuspid Valve Regurgitant Volume	ml	NUM (6.2)		
42	TVRF	Tricuspid Valve Regurgitant Fraction	%	NUM (6.2)		
43	RASV	Right Atrial Stroke Volume	ml	NUM (6.2)		
44	RAEF	Right Atrial Ejection Fraction	%	NUM (6.2)		
45	LASV	Left Atrial Stroke Volume	ml	NUM (6.2)		
46	LAEF	Left Atrial Ejection Fraction	%	NUM (6.2)		

Missing Data numeric fields –

Per sponsor agreement blank fields are known to be unavailable

Default precision for numeric fields –

Two decimal digits.

Non-numeric fields defined with code lists –

Per sponsor request, the selected text string as shown in above definition table (code column) will be output to the transfer file.

Formulas used in calculations-

Mitral Valve Regurgitant Volume (MVRV) is calculated by subtracting Q Flow Aorta Total Forward Flow Volume (QFLANF) from the stroke volume of the Left ventricle (LVSV).

Tricuspid Valve Regurgitant Volume (TVRV) is calculated by subtracting Q Flow Main Pulmonary Artery total forward flow volume (QFMPANF) from the stroke volume of the Right ventricle (RVSV).

(Variables to be used in the following formulas are being collected in the formulas above)

Mitral Valve Regurgitant Fraction (MVRF) is calculated by dividing the stroke volume of the Left ventricle (LVSV) into the Mitral Valve Regurgitant Volume (MVRV).

Tricuspid Valve Regurgitant Fraction (TVRF) is calculated by dividing the stroke volume of the Right ventricle (RVSV) into the Tricuspid Valve Regurgitant Volume (TVRV).

Left Atrial Stroke Volume (LASV) is calculated by subtracting the left atrial end-diastolic volume (LAEDV) from the left atrial end-systolic volume (LAESV).

Right Atrial Stroke Volume (RASV) is calculated by subtracting the right atrial end-diastolic volume (RAEDV) from the right atrial end-systolic volume (RAESV)

(Variables to be used in the following formulas are being collected in the formulas above)

Left Atrial Ejection Fraction (LAEF) is calculated by dividing the left atrial stroke volume (LASV) by the LA end-systolic volume (LAESV). The result is a percentage (%).

Right Atrial Ejection Fraction (RAEF) is calculated by dividing the right atrial stroke volume (RASV) by the RA end-systolic volume (RAESV). The result is a percentage (%).

PVD_LUNG_IMAGING

PVDOMICS

PVDOMICS STUDY
Lung Imaging Core (CT) Results Form #262

Instructions: This form is used by the Lung Imaging Core (LIC) to provide results following review of chest CT submitted for the PVDOMICS Study. Data will be entered into the PVDOMICS Study database.

PID

1. Identification Number

AC

2. Alphacode

VISIT_DT

3a. Date of Chest CT scan (mm/dd/yyyy)

3b. CT Scan status (1=New scan, 2=Historical scan) ..... CT_STATUS

4. Date Chest CT read by LIC radiologist ..... __ __ / __ __ / READ_DT

5. Quality of CT scan? ..... CT_QUALITY
   1=Quality of scan is complete and of good quality (all structures can be seen and measures documented)
   2=Quality of scan is adequate with only some measurements of primary structures can be determined but enough to allow adequate determination of PAH
   3=Quality of scan is inadequate and PAH determination cannot be made.

6. Type of scan (*will auto populate if F252/F253 was completed*) ..... CT_SCAN_TYPE
   1=Chest CT without contrast (Non-contrast Chest CT)
   2=Chest CT with contrast (Routine post contrast CT)
   3=Chest CT with angiogram (Chest CTA PE protocol)
   4=Chest CT without contrast (PVDOMICS RESEARCH SCAN)

7. Main pulmonary artery (PA) (diameter, cm) ..... MAIN_PA

8. Ascending aorta (diameter, cm). ..... ASCEND_AORTA

9. Ground glass (0=No, 1=Yes) ..... GROUND_GLASS

10. Traction bronchiectasis (0=No, 1=Yes) ..... TRACT_BRONC

11. Honeycombing (0=No, 1=Yes) ..... HONEYCOMBING

12. Consolidation (0=No, 1=Yes) ..... CONSOLIDATION

13. Interstitial Lung Disease (ILD) (0=No, 1=Yes) ..... ILD

    a. Most likely ILD etiology? ..... ILD_ETIOLOGY_OTH
       1=Usual interstitial pneumonia (UIP)
       2=Nonspecific interstitial pneumonia (NSIP)
       3=Hypersensitivity pneumonitis
       4=Sarcoidosis
       5=Drug toxicity
       6=Other,specify: _____
       9=Unable to determine

14. Bronchial thickening (0=No, 1=Yes) ..... BRONG_THICK

15. Emphysema (0=No, 1=Yes) ..... EMPHYSEMA

16. Mosaic attenuation (0=No, 1=Yes) ..... MOSAIC_ATTEN

17. Septal thickening (0=No, 1=Yes) ..... SEPTAL_THICK

18. Thromboembolic disease (0=No, 1=Yes, 8=N/A-cannot be determined due to type of scan) ..... THROMB_DIS
    a. Main (0=No, 1=Yes) ..... THROMB_MAIN
    b. Lobar (0=No, 1=Yes) ..... THROMB_LOBAR
    c. Segmental (0=No, 1=Yes) ..... THROMB_SEG
    d. Sub-segmental (0=No, 1=Yes) ..... THROMB_SUBSEG
19. Mediastinal adenopathy ≥1cm (0=No, 1=Yes) ..... MEDIA_ADENO
20. Cardiac enlargement (0=No, 1=Yes) ..... CARD_ENLARGE
21. Pericardial effusion (0=No, 1=Mild, 2=Moderate, 3=Severe) ..... PERI_EFF
22. Esophagus (0=No, 1=Yes) ..... ESOPHAGUS
23. Lung nodules ≥6 mm (0=No, 1=Yes) ..... LUNG_NODULES
24. Chest wall musculature-age appropriate (1=Normal, 2=Atrophic) ..... C.W._MUSCUL_AGE
25. Breast mass(es) (0=No, 1=Yes) ..... BREAST_MASS
26. Vertebral fracture(s) (0=No, 1=Yes) ..... VERT_FRACT
27. Pleural wall abnormality (0=No, 1=Yes) ..... PLEURAL_WALL
28. Chest wall subcutaneous fat (1=Normal, 2=Obese, 3=Atrophic) ..... C.W._SUBCUT_FAT
29. Chest wall or thoracic spine deformity (*for example*: kyphoscoliosis, etc) (0=No, 1=Yes) C.W._SPINE_DEF
30. Is the Chest CT suggestive of pulmonary hypertension? ..... PULM_HYPER

    0=No
    1=Unlikely PH
    2=Possibly PH
    4=Probably PH
    5=Most likely PH
    8=PH status unable to be determined due to inadequate scan (per Q5=3)

31. Was a clinical center's narrative report available at the time the images were reviewed by the CT Core radiologist? (0=No, 1=Yes) ..... NARRATIVE

Comment box added to database to document radiologists' notes. COMMENTS

200. Date this form completed (mm/dd/yyyy) ..... __/__/ COMP_DT
201. Username of radiologist completing/reviewing completeness of this form ..... COMP_USER

Core Use Only

Date Form Entered (mm/dd/yyyy) __/__/ ENTER_DT

Username of person entering this form ENTER_USER

06/06/2018 Q6 will auto populate if F252/F253 entered; Q201 'COREREV' entered if both radiologists review together; Comment box added to document radiologists' notes. Q31-code 9='Unknown' added.

PVDOMICS

PVDOMICS STUDY
Lung Imaging Core (CT) Additional Results Form #262A

Instructions: This form is used by the Lung Imaging Core (LIC) to provide additional results following review of chest CT submitted for the PVDOMICS Study. Data will be entered into the PVDOMICS Study database. This form will be entered for all participants that have CT results entered on F262.

1. Identification Number	2. Alphacode	3. Date of Chest CT scan (mm/dd/yyyy) *(date must match F262)*
PID	**AC**	**VISIT_DT**

4. Are additional Pulmonary Artery (PA) measurements available (0=No, 1=Yes)..... **PA_AVAIL** ___

5. Right PA Measurement (cm)..... **RT_PA** ___.___ ___

6. Left PA Measurement (cm)..... **LT_PA** ___.___ ___

Comments: **COMMENTS** _____

_____

_____

200. Date this form completed (mm/dd/yyyy)..... **COMP_DT** ___ ___ /___ ___ /___ ___ ___ ___

201. Username of radiologist completing/reviewing completeness of this form..... **COMP_USER** ___ ___ ___ ___ ___ ___ ___

Core Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/__ __ __ __ **ENTER_DT**

Username of person entering this form__ __ __ __ __ __ __ **ENTER_USER**

PVD_PFT

Revision of 10/27/2017

PVDOMICS

PVDOMICS STUDY
Pulmonary Function Testing Form #270

Instructions: This form should be completed for each set of Pulmonary Function Tests (PFT) **done for the PVDOMICS Study.** It should be included in the packet of materials transmitted to the Data Coordinating Center accompanied by the required printouts and tracings. Use Form 271 for reporting historical PFTs.

Note: Ideally, this test should be rescheduled for any of the following conditions, please refer back to PFT MOP Chapters:

- The participant consumed any caffeine-containing products within 6 hours
- The participant ate a large meal within 2 hours
- The participant consumed alcohol within 4 hours

1. Identification Number (PID)	2. Alphacode. (AC)	3a. Date of PFT: mm/dd/yyyy (VISIT_DT)

3. b. Did this participant attempt/complete pulmonary function testing (PFT)? (0=No, 1=Yes) ..... PFT_DONE

c. Why were the PFTs not done? ..... PFT_ND_REAS

1=Participant attempted but could not tolerate procedure
2=Physician judgment/medical contraindication
3=Logistics issue with clinical center
4=Logistics issue with participant
5=Participant refused

4. Visit type (1=Initial, 2=Other) ..... VISIT_TYPE
5. Time of day (24-hour clock) (hh:mm) ..... PFT_TM : __
6. Participant height (measured)(cm) ..... HEIGHT_CM
7. Participant weight (measured)(kg) ..... WEIGHT_KG
8. a. Is the PFT Tech name known (0=No, 1=Yes) ..... TECH_KNOWN

b. If yes, username of PFT Tech who performed test ..... TECHNOLOGIST
(Note: Username of PFT Tech is the first 6 letters of last name and first initial of first name)

Name of PFT Tech who performed test _____
(will not be entered into the database)

9. a. Ambient temperature (°C) ..... AMBIENT_TEMP
b. Barometric pressure (mmHg) ..... BAROMET_PRESS
c. Conversion factor (ATPS to BTPS) ..... ATPS_BTPS_CONV

A copy of the daily 3L syringe calibration should be made available if requested by PFT Core.

PARTICIPANT STATUS

10. a. Did participant use a prescription or non-prescription inhaled bronchodilator within 8 hours prior to testing? (0=No, 1=Yes, 9=Unknown) ..... BRONCH_USED

If NO, skip to Question 11.

b. If yes, how many hours prior to testing did participant use the bronchodilator? ..... __.__
BRONCH_HRS_PRIOR

11. Did participant smoke any tobacco (cigarettes, e-cigarettes, cigars, pipes, etc.) within 1 hour prior to testing? (0=No, 1=Yes, 9=Unknown) ..... SMOKE-PRIOR

12. Did participant exercise strenuously within 1 hour prior to testing? (0=No, 1=Yes, 9=Unknown) ..... EXERC-PRIOR

13. a. Does participant use supplemental oxygen? (0=No, 1=Yes, 9=Unknown) ..... OXYGEN

b. If yes, prescribed oxygen use (liters per minute) ..... OXYGEN-LPM

c. Was supplemental oxygen discontinued at least 10 minutes prior to testing? (0=No, 1=Yes) OXYGEN-DISC

d. If no, how many minutes before O2 discontinued prior testing? ..OXYGEN-DISC-MIN

14. a. Has the participant taken a Theophylline preparation within the past 36 hours? (0=No, 1=Yes, 9=Unknown) ..... THEOPH

If NO to Q14, skip to Question 15.

If YES to Q14, specify drug taken _____ THEOPH-SPEC

b. How many hours before first spirometry was last dose of theophylline taken? ..... THEOPH-HRS

15. a. Has participant had an acute respiratory infection (including colds, influenza, acute bronchitis, pneumonia, pleurisy or abdominal and/or chest surgery) within 2 weeks prior to the visit? (0=No, 1=Yes, 9=Unknown)? ..... RESP_INFEC

If YES, specify: _____ RESP-INFEC-SPEC

If YES to Q15, try to reschedule PFT testing for at least three weeks post-surgery or after the infection has cleared.

b. Was participant rescheduled? (0=No, 1=Yes) ..... RECHED

If NO, why not: _____ RESCHED-NO-SPEC

16. Mouthpiece size used (1=Standard, 2=Non-Standard, 9=Unknown) ..... MOUTHPIECE_SIZE

(If Non-Standard, *specify model*: MOUTHPIECE-MODEL

17. Was hemoglobin measured within 2 weeks of PFTs? (0=No, 1=Yes) ..... HGB-MEAS

Report hemoglobin value in Q23d if single breath DLCO is done.

SPIROMETRY

18. Was spirometry done? ..... SPIRO-DONE

0=No, skip to Q22
1=Yes, pre-bronchodilator (bd) only, go to Q19
2=Yes, post-bronchodilator only, go to Q19
3=Yes, both pre-bd and post-bd done, go to Q19

19. a. Participant position (1=Sitting-[*expected*], 2=Standing) ..... SPIRO-POS

b. Resting (sitting) heart rate: (bpm) ..... SPIRO-REST-HR

c. Instrument used (Instrument must be reported on Form 20 and number assigned) ..... SPIRO-INSTRUMENT

Spirometry measurements are recorded on next page.

PRE-BRONCHODILATOR (BD) SPIROMETRY: (Record the three BEST of up to eight efforts)

	TEST 1	TEST 2	TEST 3
20. a. FVC (L) (BTPS)	PRE_FVC_1 ___.___	-2 ___.___	-3
b. FEV_1 (BTPS)	PRE_FEV1_1 ___.___	-2 ___.___	-3
c. FEV_1/FVC (%)	PRE_FVC_FEV1_1 ___.___	-2 ___.___	-3
d. Forced expiratory flow (FEF 25-75) (L/S)	PREFEF_1 ___.___	-2 ___.___	-3
e. Peak Flow (L/S)	PRE_PF_1 ___.___	-2 ___.___	-3
f. Forced expiratory time (FET)	PRE_FET_1 ___.___	-2 ___.___	-3

g. If all three tests are not recorded here, state reason PRE_MISS_REAS

h. Are flow volume-loop tracings x 3 attached? (0=No, 1=Yes) PRE_FV_ATTACH

i. Are flow volume-time loop tracings x 3 attached? (0=No, 1=Yes) PRE_FVT_ATTACH

Note: If resting heart rate is ≥ 120 bpm, contact physician prior to administering bronchodilator.

POST-BRONCHODILATOR SPIROMETRY (Record the three BEST of up to eight efforts)

21. Number of minutes spirometry done post-bronchodilator treatment POST_SPIRO_MIN

a. Type of bronchodilator used POST_BRONCH_TYPE
(1=Albuterol, 2=Levosalbutamol, 3=Other, spec. POST_BRONCH_TYPE_OTH, 9=Unknown) ___

b. Method of inhalation
(1=MDI, 2=Nebulized, 3=Other (Specify): POST_INH_METH_OTH 9=Unknown) POST_INH_METH ___

	TEST 1	TEST 2	TEST 3
c. FVC (L) (BTPS)	POST_FVC_1 ___.___	-2 ___.___	-3 ___.___
d. FEV_1 (BTPS)	POST_FEV1_1 ___.___	-2 ___.___	-3 ___.___
e. FEV_1/FVC (%)	POST_FVC_FEV1_1 ___.___	-2 ___.___	-3 ___.___
f. Forced expiratory flow (FEF 25-75) (L/S)	POST_FEF_1 ___.___	-2 ___.___	-3 ___.___
g. Peak Flow (L/S)	POST_PF_1 ___.___	-2 ___.___	-3 ___.___
h. Forced expiratory time (FET)	POST_FET_1 ___.___	-2 ___.___	-3 ___.___

i. If all three tests are not recorded here, state reason POST_MISS_REAS

j. Are flow-volume loop tracings x 3 attached? (0=No, 1=Yes) POST_FV_ATTACH ___

k. Are volume-time tracings x 3 attached? (0=No, 1=Yes) POST_FVT_ATTACH ___

LUNG COMPARTMENTS

22. Were plethysmography (body box) tests done? PLETH-DONE ___

0=No, skip to Q23
1=Yes, pre-bronchodilator (bd) only
2=Yes, post-bronchodilator only
3=Yes, both pre-bd and post-bd done

Please attach all available numeric and graphic data relating to lung compartments and DLCO. Columns for both pre- and post-bronchodilators are provided if the tests are done at all. If either pre- OR post- is done, simply complete the applicable column and mark the other column "not done".

BODY (BOX) PLETHYSMOGRAPHY	PRE-BRONCHODILATOR	POST-BRONCHODILATOR
a. Participant position (1=Sit [*expected*], 2=Stand)	PLETH-PRE-POS ___	PLETH-POST-POS
b. FRC (L) (BTPS) *(Note: either FRC or TGV must be available for test to be valid.)*	PLETH-PRE-FRC	PLETH-POST-FRC
c. ERV (L)	PLETH-PRE-ERV	PLETH-POST-ERV
d. RV (box)	PLETH-PRE-RV	PLETH-POST-RV
e. SVC (L)	PLETH-PRE-SVC	PLETH-POST-SVC
f. IC (L)	PLETH-PRE-IC	PLETH-POST-IC
g. TGV (box) *(Note: either FRC or TGV must be available for test to be valid.)*	PLETH-PRE-TGV	PLETH-POST-TGV
h. TLC (box)	PLETH-PRE-TLC	PLETH-POST-TLC

i. Are all box and mouth pressure tracings/printouts attached? (0=No, 1=Yes) PLETH-PRESS-ATTACH ___

j. Are all volume-time curves/printouts attached? (0=No, 1=Yes) PLETH-VT-ATTACH

SINGLE BREATH DLCO

23. Were Single Breath DLCO tests done? (0=No, skip to Q100, 1=Yes) DLCO-DONE ___

To be measured twice at least four minutes apart. Submit uncorrected values only.

	TEST 1	TEST 2
a. Participant position (1=Sit [*expected*], 2=Stand)	___ DLCO-POS-1	___ -2
b. When was test performed? (1=Pre-BD, 2=Post-BD)	DLCO-PERF-1 ___	-2

DLCO measurements are recorded on next page

SINGLE BREATH DLCO, continued

For the following: Indicate two individual values if available OR, if not, indicate average value from printout.

	VALUE 1	VALUE 2		AVERAGE OF 2 TESTS
c. DLCO (mlCO/min/mmHg)	DLCO_1	___.__ _2	OR	___.__ _AVG
d. Hemoglobin (g/dl)	HGB			
e. DL/VA (mlCO/min/mmHg/L) (BTPS)	DLVA_1	___.__ _2	OR	___.__ _AVG
f. VA (alveolar volume)	VA_1	___.__ _2	OR	___.__ _AVG
g. Vin (inspired volume) *or IVC*	VIN_1	___.__ _2	OR	___.__ _AVG

h. Are DLCO volume-time tracings attached? (0=No, 1=Yes) DLCO_ATTACH

i. Are gas analysis curves attached (0=No, 1=Yes) GAS_ANAL_ATTACH

Comments COMMENTS

100. Date de-identified tracings transferred to DCC (mm/dd/yyyy) TRANS_DT __/__/____

200. Date form completed (mm/dd/yyyy) __/__/COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date form entered (mm/dd/yyyy) __/__/ENTER_DT

Username of person entering this form ENTER_USER

PVD_PFT_HIST

PVDOMICS

PVDOMICS STUDY
Historical Pulmonary Function Testing Form #271

Instructions: This form is completed only if a historical set of PFT results is used. Historical test data (within 1 year) from a PVDOMICS study site is acceptable in the event there has been no change in clinical status, or is acceptable (within 1 year) if no lung disease is evident upon completion of careful history and physical and HRCT. Tracing/printouts from these historical tests should be submitted to the DCC. If tracings are not available allowing for quality control, PFTs will need to be repeated for the purpose of the study.

Do not complete this form if a new set of PFTs will be completed for the PVDOMICS study.

Note: This form is designed similarly to Form 270. Please provide as much information as possible from review of PFT completed prior to enrolling in the PVDOMICS Study. The database will allow most questions to be skipped over if information is not available.

PID | AC | VISIT_DT

1. Identification Number
2. Alphacode.
3. Date of historical PFT: mm/dd/yyyy

4. Time of day (24-hour clock) (hh:mm) ..... PFT_TM
5. Participant height (measured)(cm) ..... HEIGHT_CM
6. Participant weight (measured)(kg) ..... WEIGHT_KG
7. a. Is the PFT Tech name known (0=No, 1=Yes) ..... TECH_KNOWN
   b. If yes, username of PFT Tech who performed test ..... TECHNOLOGIST
   (Note: Username of CT Tech is the first 6 letters of last name and first initial of first name)

   Name of CT Tech who performed test _____
   (will not be entered into the database)
8. a. Ambient temperature (°C) ..... AMBIENT_TEMP
   b. Barometric pressure (mmHg) ..... BAROMET_PRESS
   c. Conversion factor (ATPS to BTPS) ..... ATPS_BTPS_CONV

A copy of the daily 3L syringe calibration should be made available if requested by PFT Core.

9. Was hemoglobin measured within 2 weeks of PFTs? (0=No, 1=Yes) ..... HGB_MEAS

Report hemoglobin value in Q15d if single breath DLCO is done.

SPIROMETRY

10. Was spirometry done? ..... SPIRO_DONE
    0=No, skip to Q22
    1=Yes, pre-bronchodilator (bd) only, go to Q11
    2=Yes, post-bronchodilator only, go to Q11
    3=Yes, both pre-bd and post-bd done, go to Q11

11. a. Participant position (1=Sitting-[*expected*], 2=Standing)..... SPIRO_POS

b. Resting (sitting) heart rate: (bpm)..... SPIRO_REST_HR

PRE-BRONCHODILATOR (BD) SPIROMETRY: (Record the three BEST of up to eight efforts)

	TEST 1	TEST 2	TEST 3
12. a. FVC (L) (BTPS).....	PRE_FVC_1	PRE_FVC_2	PRE_FVC_3
b. FEV_1 (BTPS).....	PRE_FEV1_1	PRE_FEV1_2	PRE_FEV1_3
c. FEV_1/FVC (%).....	PRE_FEV1_FVC_1	PRE_FEV1_FVC_2	PRE_FEV1_FVC_3
d. Forced expiratory flow (FEF 25-75) (L/S)...	PRE_FEF_1	PRE_FEF_2	PRE_FEF_3
e. Peak Flow (L/S).....	PRE_PF_1	PRE_PF_2	PRE_PF_3
f. Forced expiratory time (FET).....	PRE_FET_1	PRE_FET_2	PRE_FET_3

g. If all three tests are not recorded here, state reason PRE_MISS_REAS

h. Are flow volume-loop tracings x 3 attached? (0=No, 1=Yes)..... PRE_FV_ATTACH

i. Are flow volume-time loop tracings x 3 attached? (0=No, 1=Yes) PRE_FVT_ATTACH

POST-BRONCHODILATOR SPIROMETRY (Record the three BEST of up to eight efforts)

13. Number of minutes spirometry done post-bronchodilator treatment..... POST_SPIRO_MIN

a. Type of bronchodilator used (1=Albuterol, 2=Levosalbutamol, 3=Other, spec. POST_BRONCH_TYPE

b. Method of inhalation (1=MDI, 2=Nebulized, 3=Other (Specify): POST_BRONCH_TYPE_OTH

POST_INH_METH

POST_INH_METH_OTH

	TEST 1	TEST 2	TEST 3
c. FVC (L) (BTPS).....	POST_FVC_1	POST_FVC_2	POST_FVC_3
d. FEV_1 (BTPS).....	POST_FEV1_1	POST_FEV1_2	POST_FEV1_3
e. FEV_1/FVC (%).....	POST_FEV1_FVC_1	POST_FEV1_FVC_2	POST_FEV1_FVC_3
f. Forced expiratory flow (FEF 25-75) (L/S).....	POST_FEF_1	POST_FEF_2	POST_FEF_3
g. Peak Flow (L/S).....	POST_PF_1	POST_PF_2	POST_PF_3
h. Forced expiratory time (FET).....	POST_FET_1	POST_FET_2	POST_FET_3

i. If all three tests are not recorded here, state reason POST_MISS_REAS

j. Are flow-volume loop tracings x 3 attached? (0=No, 1=Yes)..... POST_FV_ATTACH

k. Are volume-time tracings x 3 attached? (0=No, 1=Yes)..... POST_FVT_ATTACH

LUNG COMPARTMENTS

14. Were plethysmography (body box) tests done? ..... PLETH_DONE

0=No, skip to Q15
1=Yes, pre-bronchodilator (bd) only
2=Yes, post-bronchodilator only
3=Yes, both pre-bd and post-bd done

Please attach all available numeric and graphic data relating to lung compartments and DLCO. Columns for both pre- and post-bronchodilators are provided if the tests are done at all. If either pre- OR post- is done, simply complete the applicable column and mark the other column "not done".

BODY (BOX) PLETHYSMOGRAPHY	PRE-BRONCHODILATOR	POST-BRONCHODILATOR
a. Participant position (1=Sit [*expected*], 2=Stand)	PLETH_PREPOS	PLETH_POST-POS
b. FRC (L) (BTPS)	PLETH_PRE FRC	PLETH_POST_FRC
c. ERV (L)	PLETH_PRE_ERV	PLETH_POST_ERV
d. RV (box)	PLETH_PRE-RV	PLETH_POST_RV
e. SVC (L)	PLETH_PRESVC	PLETH_POST_SVC
f. IC (L)	PLETH_PRE_IC	PLETH_POST_IC
g. TGV (box)	PLETH_PRE_TGV	PLETH_POST_TGV
h. TLC (box)	PLETH_PRE_TLC	PLETH_POST_TLC

i. Are all box and mouth pressure tracings/printouts attached? (0=No, 1=Yes) PLETH_PRESS_ATTACH

j. Are all volume-time curves/printouts attached? (0=No, 1=Yes) ..... PLETH_VT_ATTACH

SINGLE BREATH DLCO

15. Were Single Breath DLCO tests done? (0=No, skip to Q100, 1=Yes) ..... DLCO_DONE

To be measured twice at least four minutes apart. Submit uncorrected values only.

	TEST 1	TEST 2
a. Participant position (1=Sit [*expected*], 2=Stand)	DLCO_POS_1	DLCO_POS_2
b. When was test performed? (1=Pre-BD, 2=Post-BD)	DLCO_PERF_1	DLCO_PERF_2

DLCO measurements are recorded on next page

SINGLE BREATH DLCO, continued

For the following: Indicate two individual values if available OR, if not, indicate average value from printout.

	VALUE 1	VALUE 2		AVERAGE OF 2 TESTS
c. DLCO (mlCO/min/mmHg)	DLCO_1	DLCO_2	OR	DLCO_AVG
d. Hemoglobin (g/dl))	HGB			
e. DL/VA (mlCO/min/mmHg/L) (BTPS)	DLVA_1	DLVA_2	OR	DLVA_AVG
f. VA (alveolar volume)	VA_1	VA_2	OR	VA_AVG
g. Vin (inspired volume)	VIN_1	VIN_2	OR	VIN_AVG

h. Are DLCO volume-time tracings attached? (0=No, 1=Yes) DLCO_ATTACH

i. Are gas analysis curves attached? (0=No, 1=Yes) GAS_ANAL_ATTACH

Comments COMMENTS

100. Date de-identified tracings transferred to DCC (mm/dd/yyyy) __/__/TRANS_DT

200. Date form completed (mm/dd/yyyy) __/__/COMP_DT

201. Username of person completing/reviewing completeness of this form COMP_USER

Clinical Center Use Only

Date form entered (mm/dd/yyyy) __/__/ENTER_DT

Username of person entering this form ENTER_USER

PVD_RHC, PVD_RHC_DTL

PVDOMICS

PVDOMICS STUDY
Clinical Center Right Heart Catheterization (RHC)
Results Form #280

Instructions: Review PVDOMICS MOP Chapter 100 prior to completing right heart catheterization (RHC).

Healthy volunteers will not undergo a RHC.

Heparin Use:

- If participant received heparin within 30 minutes of this test, then either wait a minimum of 30 minutes or reschedule RHC.
- If the participant received low molecular weight heparin within 8 hours of this test, then the RHC must be rescheduled. The participant must wait 8 hours after receiving low molecular weight heparin before the RHC may be done.
- If either of these situations is true, DO NOT complete this form.

PID [ ][ ][ ][ ][ ][ ] 1. Identification Number

[AC] 2. Alphacode

[ ][ ][ ][ ][ ][ ][ ][ ] 3. Date of RHC (mm/dd/yyyy) VISIT_DT

4. Did this participant undergo a right heart catheterization (RHC)? ..... RHC
(0=No, 1=Yes, 8=N/A - participant is healthy volunteer)

   a. Why was the RHC not done? ..... RHC_RSN
   1=Abnormal lab value
   2=Participant could not tolerate procedure (provide explanation at end of form)
   3=Physician judgment (provide explanation at end of form)
   4=Heparin not withheld appropriately
   5=Cannot be off of positive pressure airway device during the procedure
   6=Participant refused

5. Was this RHC completed with an invasive CPET? (0=No, 1=Yes, *also complete Form 291*)..... CPET

6. Was a left heart catheterization done in conjunction with this RHC? (0=No, 1=Yes) ..... LHC

7. Was participant taking heparin prior to RHC? ..... HEPARIN
   0=No, skip to Q8 for other medications taken
   1=Yes, taking heparin
   2=Yes, taking low molecular weight heparin (e.g. dalteparin, enoxaparin, Lovenox, etc.)

   a. Was heparin withheld for the appropriate amount of time? ..... HEP_WITHHELD
   0=No, **STOP. Reschedule or wait until 30 minutes if heparin was given OR 8 hours if low molecular weight heparin was given before attempting RHC**
   1=Yes, withheld for the appropriate amount of time

8. Has participant taken any of the following medications in the last 24 hrs (0=No, 1=Yes)..... MEDS
   a. Insulin? (0=No, 1=Yes) ..... INSULIN
   b. Anticoagulant other than heparin? (0=No, 1=Yes)..... ANTICOAG

9. Date of last meal (mm/dd/yyyy)..... __ __ / __ __ DT_LAST_MEAL

10. Time of last meal (use 24-hr clock; hh:mm)..... TM_LAST_MEAL

11. Measured height on day of RHC (cm)..... HT . _ _
12. Measured weight on day of RHC (kg)..... WT . _ _

Body Surface Area (BSA) (m2)..... BSA _ . _ _

(Note: database will calculate BSA and store in database. Write the measurement in the greyed out box on this paper CRF)

13. Measured hemoglobin on day of RHC (g/dl), if available..... HGB _

a. Where was blood taken for hemoglobin? (1=Peripheral blood, 2=PA blood sample) ... HGB_LOC

Procedure Notes

14. Is participant using oxygen at the time of this RHC? (0=No, 1=Yes, 8=N/A, never on O_2)..... OXYGEN

a. What O_2 flow rate is used during right heart catheterization (L/min)? ..... O2_FLOW

15. Venous access obtained via (1=Internal jugular vein, 2=Antecubital vein, 3=Femoral vein) ..... VENOUS_ACCESS

16. Swan-Ganz sheath French size used during RHC ..... SHEATH_SIZE

17. Swan-Ganz catheter French size used during RHC..... CATHETER_SIZE

18. Name of study site staff physician performing the RHC..... _ PHYSCIAN

(use first 6 letters of staff physician's last name and first initial)

Resting Blood Draw

19. Venous blood draw time (hh:mm, use 24-hour clock) ..... VEN_BLD_DRAW_TM

20. Was systemic arterial blood drawn? (0=No, 1=Yes)..... SYSTEMIC_BLD_DRAW

(Optional, only if arterial line already in place)

a. Systemic Arterial blood draw time (hh:mm, use 24-hour clock)..... SYSTEMIC_BLD_TM

MEASUREMENTS: All measurements will be repeated under four different conditions: Resting Right Heart Catheterization, Oxygen Challenge, Vasodilatory Challenge, and either a Fluid Challenge (Saline Loading) or an invasive Cardiopulmonary Exercise Test (iCPET). Some subjects may be excluded from the 100% Oxygen Challenge or Vasodilatory Challenge. Refer to the MOP Chapters 100 for RHC details and Chapter 111 for iCPET details.

Resting Right Heart Catheterization

21. Was a Resting Right Heart Catheterization done? (0=No, 1=Yes) ..... REST_RHC
    a. Superior Vena Cava Oxygen Saturation (SVC sat) (%) ..... SVC_SAT
    b. Fraction of Inspired Oxygen (FiO_2) (%) FIO2
    c. Pulse Oximetry Oxygen Saturation (O_2 sat) (%) ..... O2_SAT
    d. Arterial Oxygen Saturation (Art O_2) (%) *if available, if not leave blank* ..... ART_O2
    e. Systemic Systolic Blood Pressure (SBP) (mmHg) ..... SBP
    f. Systemic Diastolic Blood Pressure (DBP) (mmHg) ..... DBP
    g. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line) ..... BP_MEAS
    h. Heart Rate (bpm) ..... HT_RT
    i. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) ..... HT_RHYTHM

Pressure measurements during the resting right heart catheterization will be taken twice, once during spontaneous breathing and once during an end-expiratory breath hold.

Right Atrium Measurements:

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
22. Right Atrium (RA) Mean Pressure	RA_MP_SPONT	RA_MP_EXPIR
23. RA Peak "a wave" Pressure	RA_A_WAVE_SPONT	RA_A_WAVE_EXPIR
24. RA Peak "v wave" Pressure	RA_V_WAVE_SPONT	RA_V_WAVE_EXPIR
25. RA Oxygen Saturation (RA sat) *Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis*	RA_SAT_SPONT %	

Right Ventricle Measurements:

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
26. Right Ventricle (RV) Peak Systolic Pressure (SBP) (mmHg)	RV_SP_SPONT	RV_SP_EXPIR
27. RV End Diastolic Pressure (mmHg)	RV_END_DP_SPONT	RV_END_DP_EXPIR

Resting Right Heart Catheterization, continued

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
28. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave)	PCWP_SPONT	PCWP_EXPIR
29. PCW Peak "a wave" Pressure	PCWP_A_WAVE_SPONT	PCWP_A_WAVE_EXPIR
30. PCW Peak "v wave" Pressure	PCWP_V_WAVE_SPONT	PCWP_V_WAVE_EXPIR
31. PCWP Oxygen Saturation (PCWP sat) *Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis*	PCWP_SAT%	

PCWP OMICS Blood Draw *Draw back 3mL of waste in syringe, then 6.5mL in second syringe for analysis*

32. PCWP blood draw time (hh:mm, use 24-hour clock) ..... PCWP_DRAW_TM__ : ____

Pulmonary Artery (PA) Pressure Measurements:

Breathing Condition	Spontaneous Breathing	End–Expiratory Hold
33. Pulmonary Artery (PA) Systolic Pressure (mmHg)	PA_SP_SPONT	PA_SP_EXPIR
34. PA Diastolic Pressure (mmHg)	PA_DP_SPONT	PA_DP_EXPIR
35. PA Mean Pressure measured from Mean PA line by machine	PA_MP_MEAS_SPONT	PA_MP_MEAS_EXPIR
36. PA Mean Pressure (calculated) (calculated by PVDOMICS database; record on this form)	PA_MP_CALC_SPONT	PA_MP_CALC_SPONT
37. PA Oxygen Saturation (PA sat) *Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis*	PA_O2_SAT%	

PA OMICS Blood Draw *Draw back 3mL of waste in syringe, then 6.5mL in second syringe for analysis*

38. PA blood draw time (hh:mm, use 24-hour clock) ..... PA_DRAW_TM__ : ____

Resting Right Heart Catheterization, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

39. Were Resting RHC Thermodilution CO measurements done? (0=No, 1=Yes) ....THERMO_DONE

a. TDCO (L/min) – measurement 1 ....THERMO_MEAS_1

b. TDCO (L/min) – measurement 2 ....THERMO_MEAS_2

c. TDCO (L/min) – measurement 3 ....THERMO_MEAS_3

d. Number of measurements taken to get three measures with < 10% variability. THERMO_TOT_MEAS

Direct Fick Cardiac Output:

40. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) ....FICK_DONE

a. Resting VO_2 (measured) (ml/kg/min) ....FICK_VO2

b. Direct Fick Cardiac Output (L/min) ....FICK_OUTPUT

c. Direct Fick Cardiac Index (L/min/m^2) ....FICK_INDEX

Oxygen Challenge measurements on next page.

Oxygen Challenge

41. Was Oxygen Challenge done? (1=Yes, 2=No, contraindicated per protocol, 3=No, logistical issues) OC_DONE
    a. Fraction of Inspired Oxygen (FiO_2 sat) (%) OC_FIO2_SAT
    b. Pulse Oximetry Oxygen Saturation (O_2 sat) (%) OC_O2_SAT
    c. Arterial Oxygen Saturation (Art O_2 sat) (%) *if available, if not leave blank* OC_ARTO2_SAT
    d. Systolic Blood Pressure (SBP) (mmHg) OC_SBP
    e. Diastolic Blood Pressure (DBP) (mmHg) OC_DBP
    f. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line) OC_BP_MEAS
    g. Heart Rate (bpm) OC_HT_RATE
    h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) OC_HT_RHYTHM

All pressure measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

42. Right Atrium (RA) Mean Pressure OC_RA_MEAN_PRESS
43. RA Peak "a wave" Pressure OC_RA_A_WAVE_PRESS
44. RA Peak "v wave" Pressure OC_RA_V_WAVE_PRESS

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

45. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave) OC_PCWP_MEAN_PRESS
46. PCW Peak "a wave" Pressure OC_PCWP_A_WAVE_PRESS
47. PCW Peak "v wave" Pressure OC_PCWP_V_WAVE_PRESS

PA Measurements:

48. Pulmonary Artery (PA) Systolic Pressure (mmHg) OC_PA_SP
49. PA Diastolic Pressure (mmHg) OC_PA_DP
50. PA Mean Pressure measured from Mean PA line by machine OC_PA_MP_MEAS
51. *PA Mean Pressure* (*calculated by PVDOMICS database; record on this form*) OC_PA_MP_CALC

Oxygen Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

52. Were Oxygen Challenge Thermodilution CO measurements done? (0=No, 1=Yes) OC_THERMO_DONE
    a. TDCO (L/min) – measurement 1 ..... OC_THERMO_MEAS_1
    b. TDCO (L/min) – measurement 2 ..... OC_THERMO_MEAS_2
    c. TDCO (L/min) – measurement 3 ..... OC_THERMO_MEAS_3
    d. Number of measurements taken to get three measures with < 10% variability..... OC_THERMO_TOT_MEAS

Direct Fick Cardiac Output:

53. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) OC_FICK_DONE
    a. Resting VO_2 (measured) (ml/kg/min) ..... OC_FICK_VO2
    b. Direct Fick Cardiac Output (L/min) ..... OC_FICK_OUTPUT
    c. Direct Fick Cardiac Index (L/min/m^2) ..... OC_FICK_INDEX

Vasodilatory Challenge measurements on next page.

Vasodilatory Challenge

54. Was Vasodilatory Challenge done? (1=Yes, 2=No, contraindicated per protocol, 3=No, logistical issues) VC_DONE

a. Fraction of Inspired Oxygen (FiO_2) (%) VC_FIO2_SAT
b. Pulse Oximetry Oxygen Saturation (O_2 sat) (%) VC_O2_SAT
c. Arterial Oxygen Saturation (Art O_2) (%) *if available, if not leave blank* VC_ARTO2_SAT
d. Systolic Blood Pressure (SBP) (mmHg) VC_SBP
e. Diastolic Blood Pressure (DBP) (mmHg) VC_DBP
f. How was Blood Pressure measured? (1=Non-invasive Cuff, 2=Arterial Line) VC_BP_MEAS
g. Heart Rate (bpm) VC_HT_RATE
h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) VC_HT_RHYTHM

All pressure measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

55. Right Atrium (RA) Mean Pressure VC_RA_MEAN_PRESS
56. RA Peak "a wave" Pressure VC_RA_A_WAVE_PRESS
57. RA Peak "v wave" Pressure VC_RA_V_WAVE_PRESS

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

58. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave) VC_PCWP_MEAN_PRESS
59. PCW Peak "a wave" Pressure VC_PCWP_A_WAVE_PRESS
60. PCW Peak "v wave" Pressure VC_PCWP_V_WAVE_PRESS

PA Measurements:

61. Pulmonary Artery (PA) Systolic Pressure (mmHg) VC_PA_SP
62. PA Diastolic Pressure(mmHg) VC_PA_DP
63. PA Mean Pressure measured from Mean PA line by machine VC_PA_MP_MEAS
64. PA Mean Pressure *(calculated by PVDOMICS database; record on this form)* VC_PA_MP_CALC

Vasodilatory Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

65. Were Vasodilatory Challenge Thermodilution CO measurements done? (0=No, 1=Yes) VC_THERMO_DONE
    a. TDCO (L/min) – measurement 1 ..... VC_THERMO_MEAS_1
    b. TDCO (L/min) – measurement 2 ..... VC_THERMO_MEAS_2
    c. TDCO (L/min) – measurement 3 ..... VC_THERMO_MEAS_3
    d. Number of measurements taken to get three measures with < 10% variability VC_THERMO_TOT_MEAS

Direct Fick Cardiac Output:

66. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) ..... VC_FICK_DONE
    a. Resting VO_2 (measured) (ml/kg/min) ..... VC_FICK_VO2
    b. Direct Fick Cardiac Output (L/min) ..... VC_FICK_OUTPUT
    c. Direct Fick Cardiac Index (L/min/m^2) ..... VC_FICK_INDEX

Fluid Challenge measurements on next page.

Fluid Challenge

67. Was Fluid Challenge done? (1=Yes, 2=No, doing iCPET instead*, 3=No, logistical issues, 4=No, contraindicated per protocol) ..... FC_DONE

a. Fraction of Inspired Oxygen (FiO_2) (%) ..... FC_FIO2_SAT ___

b. Pulse Oximetry Oxygen Saturation (O_2 sat) (%) ..... FC_O2_SAT ___

c. Arterial Oxygen Saturation (Art O_2) (%) *if available, if not leave blank* ..... FC_ART_O2_SAT

d. Systolic Blood Pressure (SBP) (mmHg) ..... FC_SBP ___

e. Diastolic Blood Pressure (DBP) (mmHg) ..... FC_DBP ___

f. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line) ..... FC_BP_MEAS

g. Heart Rate (bpm) ..... FC_HT_RATE

h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) ..... FC_HT_RHYTHM

Complete Form 291 for invasive CPET.

All Pressure Measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

68. Right Atrium (RA) Mean Pressure ..... FC_RA_MEAN_PRESS ___

69. RA Peak "a wave" Pressure ..... FC_RA_A_WAVE_PRESS ___

70. RA Peak "v wave" Pressure ..... FC_RA_V_WAVE_PRESS ___

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

71. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave) ..... FC_PCWP_MEAN_PRESS

72. PCW Peak "a wave" Pressure ..... FC_PCWP_A_WAVE_PRESS

73. PCW Peak "v wave" Pressure ..... FC_PCWP_V_WAVE_PRESS

Pulmonary Artery Measurements:

74. Pulmonary Artery (PA) Systolic Pressure (mmHg) ..... FC_PA_SP ___

75. PA Diastolic Pressure (mmHg) ..... FC_PA_DP ___

76. PA Mean Pressure measured from Mean PA line by machine ..... FC_PA_MP_MEAS

77. *PA Mean Pressure (calculated by PVDOMICS database; record on this form)* FC_PA_MP_CALC

Fluid Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

78. Were Fluid Challenge Thermodilution CO Measurements done? (0=No, 1=Yes) FC_THERMO_DONE
    a. TDCO (L/min) – measurement 1 ..... FC_THERMO_MEAS_1
    b. TDCO (L/min) – measurement 2 ..... FC_THERMO_MEAS_2
    c. TDCO (L/min) – measurement 3 ..... FC_THERMO_MEAS_3
    d. Number of measurements taken to get three measures with < 10% variability FC_THERMO_TOT_MEAS

Direct Fick Cardiac Output:

79. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) FC_FICK_DONE
    a. Resting VO_2 (measured) (ml/kg/min) ..... FC_FICK_VO2
    b. Direct Fick Cardiac Output (L/min) ..... FC_FICK_OUTPUT
    c. Direct Fick Cardiac Index (L/min/m^2) ..... FC_FICK_INDEX

80. Are any RHC test data missing? ..... RHC_DATA_MISSING
    (0=No, all necessary data obtained per study protocol, 1=Yes, specify in comments on last page)

81. Were there any adverse events or unexpected problems in completing the RHC? (0=No, 1=Yes) .....
    ADVERSE_EVENTS

Please report adverse events and unexpected problems to your local IRB per local guidelines for reporting. MedDRA will be used to identify signs and symptoms.

TABLE: PVD_RHC_DTL

PID
AC
VISIT_DT

Sign/Symptom (MedDRA) *(You will be able to enter as many as needed)*	MedDRD *(auto populated by database)*
SYMPTOM	MEDDRA

82. Are any comments documented? (0=No comments, 1=Yes, specify below) ....DOC_COMMENTS

Comments for Core *(entered into database)*: COMMENTS

100. a. Username of physician* overseeing RHC ....RHC_USERNAME
(Username is the first 6 letters of physician's last name and first initial.)
*This should be the center PI or other study physician trained on the PVDOMICS RHC protocol.

b. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form ....__PHYSREV_USERNAME
(Username of physician is the first 6 letters of last name and first initial.)

101. Date file transferred to CPC Core (mm/dd/yyyy)..... __FILE_TRANS_DT

102. Username of study staff* transmitting RHC data to CPC Core..... __TRANS_USERNAME
(Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)

For DCC Use Only:

198. RHC insufficient data/unreadable per CPC?.....RHC_INSUFFICIENT

199. Date notified..... __ __/__ __ __/ INSUFF_NOTIFY_DT

200. Date this form was completed (mm/dd/yyyy) ..... __ __/__ __/COMP_DT

201. Username of person completing/reviewing completeness of this form..... __COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __/__ __/ ENTER_DT
Username of person entering this form __ __ ENTER_USER

PVDOMICS

PVDOMICS STUDY
Core Right Heart Catheterization (RHC)
Results Form #283

Instructions: This form is for use by the staff at the Cardiovascular Physiology Core (CPC) when reviewing center RHC results.

PID						AC		VISIT_DT							

1. Identification Number 2. Alphacode 3. Date of RHC (mm/dd/yyyy)

Resting Right Heart Catheterization

90. Is this RHC acceptable quality? ..... RHC_QUALITY
- 0 = No, no unusable data
- 1 = No, unacceptable: missing key data pieces
- 2 = Yes, acceptable: majority of data collected and accurate

For Core quality assessment questions I - XIII use the codes below:
- **0= No, this part of RHC was not done**
- **1= No, waveforms not received**
- **2= No, waveforms received and some data is available but missing key components (e.g., scale mean line, test condition, etc.)**
- **3= No, waveforms received and some data is available but waveforms or printout poor quality or illegible**
- **4= Yes, waveforms received and of good quality**

21. If Resting Right Heart Catheterization done:

h. Heart Rate (bpm) ..... HT_RT

i. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) ..... HT_RHYTHM

Right Atrium Measurements: RA_SPONT_WAVE_OK

Ia. *(core only)* Are the waveforms for resting RHC right atrium spontaneous breathing acceptable? ...___

Ib. *(core only)* Are the waveforms for resting RHC right atrium end-expiratory hold acceptable? .....___

Note: If Ia = 0 or 1 and Ib = 0 or 1, skip to IIa. RA_EXPIR_WAVE_OK

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
22. Right Atrium (RA) Mean Pressure	RA_MP_SPONT	RA_MP_EXPIR
23. RA Peak "a wave" Pressure	RA_A_WAVESPONT	RA_A_WAVE_EXPIR
24. RA Peak "v wave" Pressure	RA_V_WAVE_SPONT	RA_V_WAVE_EXPIR
25. RA Oxygen Saturation (RA sat)	RA_SAT_SPONT %	

Right Ventricle Measurements: RV_SPONT_WAVE_OK

IIa. *(core only)* Are the waveforms for resting RHC right ventricle spontaneous breathing acceptable?___

IIb. *(core only)* Are the waveforms for resting RHC right ventricle end-expiratory hold acceptable?....___

Note: If IIa = 0 or 1 and IIb = 0 or 1, skip to IIIa. RV_EXPIR_WAVE_OK

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
26. Right Ventricle (RV) Peak Systolic Pressure (SBP) (mmHg)	RV_SP_SPONT	RV_SP_EXPIR
27. RV End Diastolic Pressure (mmHg)	RV_END_DP_SPONT	RV_END_DP_EXPIR

Pulmonary Capillary Wedge Pressure (PCWP) Measurements: PCWP_SPONT_WAVE_OK

IIIa. *(core only)* Are the waveforms for resting RHC PCWP spontaneous breathing acceptable? .....___

IIIb. *(core only)* Are the waveforms for resting RHC PCWP end-expiratory hold acceptable? .....___

Note: If IIIa = 0 or 1 and IIIb = 0 or 1, skip to IVa PCWP_EXPIR_WAVE_OK

Breathing Condition	a. Spontaneous Breathing	b. End–Expiratory Hold
28. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave)	PCWP_SPONT	PCWP_EXPIR
29. PCW Peak "a wave" Pressure	PCWP_A_WAVE_SPONT	PCWP_A_WAVE_EXPIR
30. PCW Peak "v wave" Pressure	PCWP_V_WAVE_SPONT	PCWP_V_WAVE_EXPIR
31. PCWP Oxygen Saturation (PCWP sat)	PCWP_SAT %	

Pulmonary Artery (PA) Pressure Measurements: PA_SPONT_WAVE_OK

IVa. *(core only)* Are the waveforms for resting RHC PA spontaneous breathing acceptable?.....___

IVb. *(core only)* Are the waveforms for resting RHC PA end-expiratory hold acceptable? .....___

Note: If IVa = 0 or 1 and IVb = 0 or 1, skip to Q39 PA_EXPIR_WAVE_OK

Breathing Condition	Spontaneous Breathing	End–Expiratory Hold
33. Pulmonary Artery (PA) Systolic Pressure (mmHg)	PA_SP_SPONT	PA_SP_EXPIR
34. PA Diastolic Pressure (mmHg)	PA_DP_SPONT	PA_DP_EXPIR

35. PA Mean Pressure measured from Mean PA line by machine	PA_MP_MEAS_SPONT	PA_MP_MEAS_EXPIR

Thermodilution Cardiac Output:

39. If Resting RHC Thermodilution CO measurements done:
    a. TDCO (L/min) – measurement 1 ..... THERMO_MEAS_1
    b. TDCO (L/min) – measurement 2 ..... THERMO_MEAS_2
    c. TDCO (L/min) – measurement 3 ..... THERMO_MEAS_3
    d. *(core only)* Is there less than 10% variability in recorded TDCO measurements? (0=No, 1=Yes) ... THERMO_OK

Direct Fick Cardiac Output:

40. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) ..... FICK_DONE
    b. Direct Fick Cardiac Output (L/min) ..... FICK_OUTPUT
    c. Direct Fick Cardiac Index (L/min/m^2) ..... FICK_INDEX

Oxygen Challenge

41. If Oxygen Challenge done:
    g. Heart Rate (bpm) ..... OC_HT_RATE
    h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) ... OC_HT_RHYTHM

Right Atrium Measurements:

V. *(core only)* Are the waveforms for oxygen challenge right atrium acceptable? ... OC_RA_OK

Note: If V = 0 or 1, skip to VI

42. Right Atrium (RA) Mean Pressure ..... OC_RA_MEAN_PRESS
43. RA Peak "a wave" Pressure ..... OC_RA_A_WAVE_PRESS
44. RA Peak "v wave" Pressure ..... OC_RA_V_WAVE_PRESS

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

VI. *(core only)* Are the waveforms for oxygen challenge PCWP acceptable? ... OC_PCWP_OK

Note: If VI = 0 or 1, skip to VII

45. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave) ... OC_PCWP_MEAN_PRESS
46. PCW Peak "a wave" Pressure ..... OC_PCWP_A_WAVE_PRESS
47. PCW Peak "v wave" Pressure ..... OC_PCWP_V_WAVE_PRESS

PA Measurements:

VII. *(core only)* Are the waveforms for oxygen challenge PA acceptable? ..... OC_PA_OK

Note: If VII = 0 or 1, skip to Q52

48. Pulmonary Artery (PA) Systolic Pressure (mmHg) ..... OC_PA_SP

49. PA Diastolic Pressure (mmHg) ..... OC_PA_DP

50. PA Mean Pressure measured from Mean PA line by machine ..... OC_PA_MP_MEAS

Thermodilution Cardiac Output:

52. If Oxygen Challenge Thermodilution CO measurements done:

a. TDCO (L/min) – measurement 1 ..... OC_THERMO_MEAS_1

b. TDCO (L/min) – measurement 2 ..... OC_THERMO_MEAS_2

c. TDCO (L/min) – measurement 3 ..... OC_THERMO_MEAS_3

d. *(core only)* Is there less than 10% variability in recorded TDCO measurements? (0=No, 1=Yes) ... OC_THERMO_OK

Direct Fick Cardiac Output:

53. If Direct Fick Cardiac Output Measurements done:

b. Direct Fick Cardiac Output (L/min) ..... OC_FICK_OUTPUT

c. Direct Fick Cardiac Index (L/min/m^2) ..... OC_FICK_INDEX

Vasodilatory Challenge

54. Is vasodilatory challenge done:

g. Heart Rate (bpm) ..... VC_HT_RATE

h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) ..... VC_HT_RHYTHM

Right Atrium Measurements:

VIII. *(core only)* Are the waveforms for vasodilatory challenge right atrium acceptable? ... VC_RA_OK

Note: If VIII = 0 or 1, skip to IX

55. Right Atrium (RA) Mean Pressure ..... VC_RA_MEAN_PRESS

56. RA Peak "a wave" Pressure ..... VC_RA_A_WAVE_PRESS

57. RA Peak "v wave" Pressure ..... VC_RA_V_WAVE_PRESS

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

IX. *(core only)* Are the waveforms for vasodilatory challenge PCWP acceptable? ..VC_PCWP_OK

Note: If IX = 0 or 1, skip to X

58. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave).....VC_PCWP_MEAN_PRESS

59. PCW Peak "a wave" Pressure.....VC_PCWP_A_WAVE_PRESS

60. PCW Peak "v wave" Pressure.....VC_PCWP_V_WAVE_PRESS

PA Measurements:

X. Are the waveforms for vasodilatory challenge PA acceptable? .....VC_PA_OK.....

Note: If X = 0 or 1, skip to Q65

61. Pulmonary Artery (PA) Systolic Pressure (mmHg).....VC_PA_SP___

62. PA Diastolic Pressure(mmHg).....VC_PA_DP___

63. PA Mean Pressure measured from Mean PA line by machine...VC_PA_MP_MEAS___

Thermodilution Cardiac Output:

65. If Vasodilatory Challenge Thermodilution CO measurements done:

a. TDCO (L/min) – measurement 1 .....VC_THERMO_MEAS_1___

b. TDCO (L/min) – measurement 2.....VC_THERMO_MEAS_2___

c. TDCO (L/min) – measurement 3.....VC_THERMO_MEAS_3___

d. *(core only)* Is there less than 10% variability in recorded TDCO measurements? (0=No, 1=Yes) ...___

VC_THERMO_OK

Direct Fick Cardiac Output:

66. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) ....VC_FICK_DONE

a. Direct Fick Cardiac Output (L/min).....VC_FICK_VO2___

b. Direct Fick Cardiac Index (L/min/m^2).....VC_FICK_INDEX

Continue on next page

Fluid Challenge

67. If fluid challenge done:
    g. Heart Rate (bpm) ..... FC_HT_RATE
    h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other)..... FC_HT_RHYTHM

Right Atrium Measurements:

XI. *(core only)* Are the waveforms for fluid challenge RA acceptable?..... FC_RA_OK

Note: If XI = 0 or 1, skip to XII

68. Right Atrium (RA) Mean Pressure ..... FC_RA_MEAN_PRESS
69. RA Peak "a wave" Pressure..... FC_RA_A_WAVE_PRESS
70. RA Peak "v wave" Pressure..... FC_RA_V_WAVE_PRESS

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

XII. *(core only)* Are the waveforms for fluid challenge PCWP acceptable? FC_PCWP_OK

Note: If XII = 0 or 1, skip to XIII

71. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave)... FC_PCWP_MEAN_PRESS
72. PCW Peak "a wave" Pressure..... FC_PCWP_A_WAVE_PRESS
73. PCW Peak "v wave" Pressure..... FC_PCWP_V_WAVE_PRESS

Pulmonary Artery Measurements:

XIII. *(core only)* Are the waveforms for fluid challenge PA acceptable? ..... FC_PA_OK

Note: If XIII = 0 or 1, skip to Q78

74. Pulmonary Artery (PA) Systolic Pressure (mmHg)..... FC_PA_SP
75. PA Diastolic Pressure (mmHg)..... FC_PA_DP
76. PA Mean Pressure measured from Mean PA line by machine..... FC_PA_MP_MEAS

Thermodilution Cardiac Output:

78. If Fluid Challenge Thermodilution CO Measurements done:
    a. TDCO (L/min) – measurement 1 ..... FC_THERMO_MEAS_1
    b. TDCO (L/min) – measurement 2..... FC_THERMO_MEAS_2
    c. TDCO (L/min) – measurement 3..... FC_THERMO_MEAS_3
    d. *(core only)* Is there less than 10% variability in recorded TDCO measurements? (0=No, 1=Yes) ...___

FC_THERMO_OK

Direct Fick Cardiac Output:

79. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) FC_FICK_DONE

b. Direct Fick Cardiac Output (L/min) ..... FC_FICK_OUTPUT

c. Direct Fick Cardiac Index (L/min/m^2) ..... FC_FICK_INDEX

85. Are any comments documented? (0=No comments, 1=Yes, specify below) DOC_COMMENTS

Core Comments *(entered into database)*: COMMENTS

114. Username of fellow reviewing the RHC ..... FELLOW_USERNAME
(Username of physician is the first 6 letters of last name and first initial.)

115. Username of staff physician reviewing the RHC ..... STAFF_USERNAME
(Username of physician is the first 6 letters of last name and first initial.)

116. Date final Core review completed (mm/dd/yyyy) ..... _ _/_ _/FINAL_DT

200. Date this form was completed (mm/dd/yyyy) ..... _ _/_ _/_ _/COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Core Use Only

Date Form Entered (mm/dd/yyyy) _ _/_ _/_ _/ ENTER_DT

Username of person entering this form ENTER_USER

PVD_CPET_NONINV

PVDOMICS

PVDOMICS STUDY
Center Cycle Ergometer Non-Invasive Cardiopulmonary Exercise Test (CPET) Procedure Notes #290

Instructions: Review PVDOMICS MOP Chapter 110 prior to completing Cardiopulmonary Exercise Test (CPET). This worksheet/form is used for **non-invasive CPET results**. Invasive CPET results are reported on Form 291.

PID | AC | VISIT_DT

1. Identification Number
2. Alphacode
3. Date of CPET (mm/dd/yyyy)

4. Did this participant undergo a non-invasive CPET? (0=No, 1=Yes) ..... CPET
   a. If no, why was the CPET not done? ..... ND_REAS
      1=Abnormal resting ECG
      2=Physically unable to cycle (e.g. arthritis)
      3=Known contraindication to exercise (e.g. exercise induced arrhythmia or exertional syncope)
      4=Other contraindication or physician judgment (provide explanation in comments box at end of form)
      5=Logistics issue (provide explanation in comments box at end of form)
5. Date of last meal (mm/dd/yyyy)..... LAST_MEAL_DT
6. Time of last meal (use 24-hr clock; hh:mm) ..... LAST_MEAL_TM
7. Did participant exercise within the last 8 hours? (0=No, 1=Yes)..... EXER_8HR
8. Is participant using oxygen at the time of this CPET? (0=No, 1=Yes, 8=N/A, never on O2) .... OXYGEN
   a. What O_2 flow is being used during CPET (L/min)? ..... OXYGEN_FLOW
9. How was blood pressure measured during the CPET? ..... BP_TYPE
   (1=Manual blood pressure cuff, 2=Automatic blood pressure cuff)

For the following question, one interval is defined as the time spent at a work load (wattage).

10. Which ramp protocol is being used for this test?..... RAMP_PROT
    1=10 watts/interval
    2=15 watts/interval
    3=20 watts/interval
    4=25 watts/interval (***this response is considered a PVDOMICS Study DEVIATION***)

Continued on Next Page

All data should be captured during the last 30 sec of each interval (e.g. between 1:30 and 2:00)

Time Elapsed	Work Rate	Heart Rate	Pulse O_2 sat	SBP	DBP	Dyspnea (Borg scale)	RPE (Borg scale)
(min)	(watts)	(bpm)	(%)	(mmHg)	(mmHg)	(0-10)	(0-10)
Pre-Exercise							
-1	PRE1_ Rest WR	PRE1_ HR	PRE1_ SAT	PRE1_ SBP	PRE1_ DBP	PRE1_ DYSP	PRE1_ RPE
Exercise							
0	EXER0_ WR	EXER0_ HR	EXER0_ SAT	EXER0_ SBP	EXER0_ DBP	EXER0_ DYSP	EXER0_ RPE
	Start ramp						
2	EXER2_ WR	EXER2_ HR	EXER2_ SAT	EXER2_ SBP	EXER2_ DBP	EXER2_ DYSP	EXER2_ RPE
4	EXER4_ WR	EXER4_ HR	EXER4_ SAT	EXER4_ SBP	EXER4_ DBP	EXER4_ DYSP	EXER4_ RPE
6	EXER6_ WR	EXER6_ HR	EXER6_ SAT	EXER6_ SBP	EXER6_ DBP	EXER6_ DYSP	EXER6_ RPE
8	EXER8_ WR	EXER8_ HR	EXER8_ SAT	EXER8_ SBP	EXER8_ DBP	EXER8_ DYSP	EXER8_ RPE
10	EXER10_ WR	EXER10_ HR	EXER10_ SAT	EXER10_ SBP	EXER10_ DBP	EXER10_ DYSP	EXER10_ RPE
12	EXER12_ WR	EXER12_ HR	EXER12_ SAT	EXER12_ SBP	EXER12_ DBP	EXER12_ DYSP	EXER12_ RPE
Recovery							
+1	REC1_ WR	REC1_ HR	REC1_ SAT	REC1_ SBP	REC1_ DBP	REC1_ DYSP	REC1_ RPE
+2	REC2_ WR	REC2_ HR	REC2_ SAT	REC2_ SBP	REC2_ DBP	REC2_ DYSP	REC2_ RPE
+3	REC3_ Rest WR	REC3_ HR	REC3_ SAT	REC3_ SBP	REC3_ DBP	REC3_ DYSP	REC3_ RPE
+4	REC4_ Rest WR	REC4_ HR	REC4_ SAT	REC4_ SBP	REC4_ DBP	REC4_ DYSP	REC4_ RPE
+5	REC5_ Rest WR	REC5_ HR	REC5_ SAT	REC5_ SBP	REC5_ DBP	REC5_ DYSP	REC5_ RPE
Peak							
_ _ : _ _ minutes : seconds	PEAK_ WR	PEAK_ HR	PEAK_ SAT	PEAK_ SBP	PEAK_ DBP	PEAK_ DYSP	PEAK_ RPE

PEAK_TIME_MIN

PEAK_TIME_SEC

Continued on Next Page

CPET TEST RESULTS:

11. Did RER reach or exceed 1.10? (0=No, 1=Yes, 9=Unknown) ..... PER_RCH_EXCD

12. Primary reason for exercise termination (select one)..... EXER_TERM

1=End of CPET protocol
2=Fatigue
3=Dyspnea
4=Chest Pain
5=Lower Extremity Pain
6=Syncope/Near Syncope
7=Physician's or technician's discretion

13. Symptoms at end of exercise? (0=No, 1=Yes)..... SYMPTOMS

a. Chest pain (0=No, 1=Yes) ..... SYMP_CHEST

b. Dizziness (0=No, 1=Yes)..... SYMP_DIZ

c. Dyspnea (0=No, 1=Yes) ..... SYMP_DYSP

d. Near syncope (0=No, 1=Yes) ..... SYMP_SYNC

e. Lower extremity claudication (cramping) (0=No, 1=Yes) ..... SYMP_CLAUD

f. Lower extremity joint/leg pain (0=No, 1=Yes) ..... SYMP_PAIN

g. Other musculoskeletal pain (e.g. back or hip pain) (0=No, 1=Yes) SYMP_OTH_MSPAIN

14. a. Username of staff performing this CPET evaluation ..... STAFF_PERF
(Note: staff username is the first 6 letters of last name and first initial of first name.)

b. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form ..... PHYS_REV
(Username of physician is the first 6 letters of last name and first initial.)

15. Username of staff transferring CPET data to CPC Core ..... STAFF_TRANS
(Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)

16. Date CPET data transferred to CPC Core (mm/dd/yyyy) ..... __ __/TRANS_DT

17. Are any comments documented? (0=No comments, 1=Yes, specify below) ..... COMMENTS_DOC

Comments COMMENTS

200. Date form completed (mm/dd/yyyy) ..... __ __/__ __/COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) __ __/__ __/ENTER_DT

Username of person entering this form ENTER_USER

08/01/2018, added to Q10, code 4=25 watts/interval ***(this response is considered a PVDOMICS Study DEVIATION)***

Modified Borg Scale for use during CPET or iCPET

Modified Borg Scale

0	Nothing at all
0.5	Very, very slight
1	Very mild
2	Mild
3	Moderate
4	Somewhat severe
5	Strong
6	-
7	Severe
8	-
9	Extremely severe
10	So severe you need to stop

Use this scale to measure both perceived dyspnea and rate of perceived exertion (RPE) before, during, and after exercise.

To assess dyspnea score ask the participant: "Using this scale from 0-10, where 0 is none at all and 10 is maximal, what number best describes your current shortness of breath?"

To assess the rate of perceived exertion (RPE) score ask the participant: "Using this scale from 0-10, where 0 is none at all and 10 is maximal, what number best describes your current level of fatigue?"

Revision of 05/24/2018

PVD_CPET_NONINV_ADD

Form #290A
Page 1 of 1

PVDOMICS

PVDOMICS STUDY
Addendum to Center Cycle Ergometer Non-Invasive Cardiopulmonary Exercise Test (CPET) Procedure Notes #290A

Instructions: This worksheet/form is used for additional **non-invasive CPET results**. This form should not be completed if F290 reports that CPET was not done for this participant.

PID [ ][ ][ ][ ][ ][ ] AC [ ][ ] [ ][ ][ ][ ][ ][ ][ ][ ] VISIT_DT

1. Identification Number 2. Alphacode 3. Date of CPET (mm/dd/yyyy)

4. Is the additional information for this CPET available? (0=No, *skip to Q200,* 1=Yes)..... CPET_ADD

All data should be captured during the last 30 sec of each interval (e.g. between 1:30 and 2:00)

Time Elapsed (min)	VO_2 (ml/kg/min)
Pre-Exercise	
-1	PRE1_VO2
Exercise	
0	EXER0_VO2

Time Elapsed (min)	VO_2 (ml/kg/min)
Start ramp	
2	EXER2_VO2
4	EXER4_VO2
6	EXER6_VO2
8	EXER8_VO2
10	EXER10_VO2
12	EXER12_VO2

Time Elapsed (min)	VO_2 (ml/kg/min)
Recovery	
+1	REC1_VO2
+2	REC2_VO2
+3	REC3_VO2
+4	REC4_VO2
+5	REC5_VO2
Peak	
___ : ___ minutes : seconds	PEAK_VO2

PEAK_TIME_MIN
PEAK_TIME_SEC

5. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form ..... PHYS_REVIEW
(Note: *username of physician is the first 6 letters of last name and first initial.)*

6. Are any comments documented? (0=No comments, 1=Yes, specify below) ..... COMMENTS_DOC

Comments COMMENTS

200. Date form completed (mm/dd/yyyy) ..... __ __ / __ __ / COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) __ __ / __ __ / ENTER_DT
Username of person entering this form ENTER_USER

PVD_CPET_INV

PVDOMICS

PVDOMICS STUDY
Center Cycle Ergometer Invasive Cardiopulmonary Exercise Test (iCPET) Procedure Notes #291

Instructions: Review PVDOMICS MOP Chapters 110 (non-invasive CPET) and 111 (invasive CPET) prior to completing Invasive Cardiopulmonary Exercise Test (iCPET). This worksheet/form is used to report **invasive CPET results**. *Non-invasive CPET results are reported on Form 290.*

Note: Form 280 (RHC) must be entered into the database before this form (F291) can be entered.

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of iCPET (mm/dd/yyyy)

4. Did this participant undergo an iCPET? (0=No, 1=Yes) ICPET
   a. If no, why was the iCPET not done? ND_REAS
      1=Abnormal resting ECG
      2=Physically unable to cycle (e.g. arthritis)
      3=Known contraindication to exercise (e.g. exercise induced arrhythmia or exertional syncope)
      4=Other contraindication or physician judgment (provide explanation in comments box at end of form)
      5=Logistics issue (provide explanation in comments box at end of form)

5. Did participant exercise within the last 8 hours? (0=No, 1=Yes) EXER_8HR

6. Participant position during iCPET? (1=Upright [recommended], 2=Supine) POSITION

7. Is participant using oxygen at the time of this iCPET? (0=No, 1=Yes, 8=N/A, never on O2) OXYGEN
   a. What O_2 flow is being used during iCPET (L/min)? OXYGEN_FLOW

8. How was blood pressure measured during the iCPET? BP_TYPE
   (1=Manual blood pressure cuff, 2=Automatic blood pressure cuff, 3=Arterial line)

For the following question, one interval is defined as the time spent at a work load (wattage).

9. Which ramp protocol is being used for this test? RAMP_PROT
   1=10 watts/interval
   2=15 watts/interval
   3=20 watts/interval
   4=25 watts/interval (***this response is considered a PVDOMICS Study DEVIATION***)

Continued on Next Page

All data should be captured during the last 30 sec of each interval

Time Elapsed	Work Rate	Heart Rate	SpO_2	SBP	DBP	Dyspnea (Borg scale)	RPE (Borg scale)	mPAP	PCWP	SvO_2	SaO_2	RAP
(min)	(Watts)	(bpm)	(%)	(mmHg)	(mmHg)	(0-10)	(0-10)	(mmHg)	(mmHg)	(%)	(%)	(mmHg)
Pre-Exercise (Resting)												
-1	Rest											
Exercise												
0	0											
Start ramp												
2												
4												
6												
8												
10												
12												
Recovery												
+1	0											
+2	0											
+3	Rest											
+4	Rest											
+5	Rest											
Peak												
___ : ___ minutes : seconds												

Continued on Next Page

All data should be captured during the last 30 sec of each interval

Time Elapsed	Work Rate	Heart Rate	SpO_2	SBP	DBP	Dyspnea (Borg scale)	RPE (Borg scale)	mPAP	PCWP	SvO_2	SaO_2	RAP
(min)	(Watts)	(bpm)	(%)	(mmHg)	(mmHg)	(0-10)	(0-10)	(mmHg)	(mmHg)	(%)	(%)	(mmHg)
Pre-Exercise (Resting)												
-1	Rest	PRE1_HR	PRE1_SPO2	PRE1_SBP	PRE1_DBP	PRE1_DYSP	PRE1_RPE	PRE1_MPAP	PRE1_PCWP	PRE1_SVO2	PRE1_SAO2	PRE1_RAP
Exercise												
0	EXER0_WR	EXER0_HR	EXER0_SPO2	EXER0_SBP	EXER0_DBP	EXER0_DYSP	EXER0_RPE	EXER0_MPAP	EXER0_PCWP	EXER0_SVO2	EXER0_SAO2	EXER0_RAP
Start ramp												
2	EXER2_WR	EXER2_HR	EXER2_SPO2	EXER2_SBP	EXER2_DBP	EXER2_DYSP	EXER2_RPE	EXER2_MPAP	EXER2_PCWP	EXER2_SVO2	EXER2_SAO2	EXER2_RAP
4	EXER4_WR	EXER4_HR	EXER4_SPO2	EXER4_SBP	EXER4_DBP	EXER4_DYSP	EXER4_RPE	EXER4_MPAP	EXER4_PCWP	EXER4_SVO2	EXER4_SAO2	EXER4_RAP
6	EXER6_WR	EXER6_HR	EXER6_SPO2	EXER6_SBP	EXER6_DBP	EXER6_DYSP	EXER6_RPE	EXER6_MPAP	EXER6_PCWP	EXER6_SVO2	EXER6_SAO2	EXER6_RAP
8	EXER8_WR	EXER8_HR	EXER8_SPO2	EXER8_SBP	EXER8_DBP	EXER8_DYSP	EXER8_RPE	EXER8_MPAP	EXER8_PCWP	EXER8_SVO2	EXER8_SAO2	EXER8_RAP
10	EXER10_WR	EXER10_HR	EXER10_SPO2	EXER10_SBP	EXER10_DBP	EXER10_DYSP	EXER10_RPE	EXER10_MPAP	EXER10_PCWP	EXER10_SVO2	EXER10_SAO2	EXER10_RAP
12	EXER12_WR	EXER12_HR	EXER12_SPO2	EXER12_SBP	EXER12_DBP	EXER12_DYSP	EXER12_RPE	EXER12_MPAP	EXER12_PCWP	EXER12_SVO2	EXER12_SAO2	EXER12_RAP
Recovery												
+1	REC1_WR	REC1_HR	REC1_SPO2	REC1_SBP	REC1_DBP	REC1_DYSP	REC1_RPE					
+2	REC2_WR	REC2_HR	REC2_SPO2	REC2_SBP	REC2_DBP	REC2_DYSP	REC2_RPE	REC2_MPAP	REC2_PCWP			REC2_RAP
+3	REC3_Rest WR	REC3_HR	REC3_SPO2	REC3_SBP	REC3_DBP	REC3_DYSP	REC3_RPE					
+4	REC4_Rest WR	REC4_HR	REC4_SPO2	REC4_SBP	REC4_DBP	REC4_DYSP	REC4_RPE					
+5	REC5_Rest WR	REC5_HR	REC5_SPO2	REC5_SBP	REC5_DBP	REC5_DYSP	REC5_RPE	REC5_MPAP	REC5_PCWP	REC5_SVO2	REC5_SAO2	REC5_RAP
Peak	~~PEAK_DRAW_TM~~											
_:_ minutes : seconds	PEAK_WR	PEAK_HR	PEAK_SPO2	PEAK_SBP	PEAK_DBP	PEAK_DYSP	PEAK_RPE	PEAK_MPAP	PEAK_PCWP	PEAK_SVO2	PEAK_SAO2	PEAK_RAP

PEAK_TIME_MIN
PEAK_TIME_SEC

Continued on Next Page

08/01/2018, added to Q9, code 4=25 watts/interval ***(this response is considered a PVDOMICS Study DEVIATION)***

Peak Exercise OMICS Blood Draw

10. Blood draw time (hh:mm, use 24-hour clock) ..... PEAK_DRAW_TM

Post-Exercise OMICS Blood Draw

11. Blood draw time (hh:mm, use 24-hour clock) ..... POST_DRAW_TM

Direct Fick Cardiac Output: Cardiac output is calculated via the direct Fick method using co-oximeter measured SaO_2 and $S\bar{v}\ O_2$ and measured VO_2.

12. Were Direct Fick Cardiac Output Measurements done during this iCPET? (0=No, 1=Yes) ..... DFCO_MEAS_DN

	At Baseline	At Peak Exercise	At Recovery
a. VO_2 value used (ml/kg/min)	VO2_BASE	VO2_EXER	VO2_REC
b. Direct Fick Cardiac Output (L/min)	DFCO_BASE	DFCO_EXER	DFCO_REC
c. Direct Fick Cardiac Index (L/min/m^2) *(calculated by PVDOMICS database; record on this form)*	CALC_DFCI_BASE	CALC_DFCI_EXER	CALC_DFCI_REC

iCPET TEST RESULTS:

13. Did RER reach or exceed 1.10? (0=No, 1=Yes, 9=Unknown) ..... RER_RCH_EXCD

14. Primary reason for exercise termination (select one) ..... EXER_TERM

1=End of iCPET protocol
2=Fatigue
3=Dyspnea
4=Chest Pain
5=Lower Extremity Pain
6=Syncope/Near Syncope
7=Physician's or technician's discretion

15. Symptoms at end of exercise? (0=No, 1=Yes) ..... SYMPTOMS

a. Chest pain (0=No, 1=Yes) ..... SYMP_CHEST
b. Dizziness (0=No, 1=Yes) ..... SYMP_DIZ
c. Dyspnea (0=No, 1=Yes) ..... SYMP_DYSP
d. Near syncope (0=No, 1=Yes) ..... SYMP_SYNC
e. Lower extremity claudication (cramping) (0=No, 1=Yes) ..... SYMP_CLAUD
f. Lower extremity joint/leg pain (0=No, 1=Yes) ..... SYMP_PAIN
g. Other musculoskeletal pain (e.g. back or hip pain) (0=No, 1=Yes) ..... SYMP_OTH_MSPAIN

08/01/2018, added to Q9, code 4=25 watts/interval ***(this response is considered a PVDOMICS Study DEVIATION)***

16. a. Username of staff performing this iCPET evaluation ..... STAFF_PERF
(Note: staff username is the first 6 letters of last name and first initial of first name.)

b. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form ..... _ _ _ _ _ _ _ _ _
(Username of physician is the first 6 letters of last name and first initial.)

17. Username of staff transferring iCPET data to CPC Core ..... STAFF_TRANS
(Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)

18. Date iCPET data transferred to CPC Core (mm/dd/yyyy) ..... _ _/_ _/TRANS_DT

19. Are any comments documented? (0=No comments, 1=Yes, specify below) ..COMMENT_DOC

Comments COMMENTS

200. Date form completed (mm/dd/yyyy) ..... _ _/_ _/COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

Clinical Center Use Only
Date Form Entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT
Username of person entering this form ENTER_USER

08/01/2018, added to Q9, code 4=25 watts/interval ***(this response is considered a PVDOMICS Study DEVIATION)***

Modified Borg Scale for use during CPET or iCPET

Modified Borg Scale

0	Nothing at all
0.5	Very, very slight
1	Very mild
2	Mild
3	Moderate
4	Somewhat severe
5	Strong
6	-
7	Severe
8	-
9	Extremely severe
10	So severe you need to stop

Use this scale to measure both perceived dyspnea and rate of perceived exertion (RPE) before, during, and after exercise.

To assess dyspnea score ask the participant: "Using this scale from 0-10, where 0 is none at all and 10 is maximal, what number best describes your current shortness of breath?"

To assess the rate of perceived exertion (RPE) score ask the participant: "Using this scale from 0-10, where 0 is none at all and 10 is maximal, what number best describes your current level of fatigue?"

Revision of 05/24/2018

PVD_CPET_INV_ADD

PVDOMICS

PVDOMICS STUDY
Addendum to Center Cycle Ergometer Invasive Cardiopulmonary Exercise Test (iCPET) Procedure Notes #291A

Instructions: This worksheet/form is used to report additional **invasive CPET results**. This form should not be completed if F291 reports that iCPET was not done for this participant.

Note: Form 280 (RHC) must be entered into the database before this form (F291A) can be entered.

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date of iCPET (mm/dd/yyyy)

4. Is the additional information for this iCPET available? (0=No, 1=Yes) ..... ICPET_ADD ___
If Q4 = 0, skip to Q200

All data should be captured during the last 30 sec of each interval

Time Elapsed	sPAP	dPAP	VO_2
(min)	(mmHg)	(mmHg)	(ml/kg/min)
Pre-Exercise (Resting)			
-1	PRE1_SPAP	PRE1_DPAP	PRE1_VO2
Exercise			
0	EXER0_SPAP	EXER0_DPAP	EXER0_VO2
Start ramp			
2	EXER2_SPAP	EXER2_DPAP	EXER2_VO2
4	EXER4_SPAP	EXER4_DPAP	EXER4_VO2
6	EXER6_SPAP	EXER6_DPAP	EXER6_VO2
8	EXER8_SPAP	EXER8_DPAP	EXER8_VO2
10	EXER10_SPAP	EXER10_DPAP	EXER10_VO2
12	EXER12_SPAP	EXER12_DPAP	EXER12_VO2

Time Elapsed	sPAP	dPAP	VO_2
(min)	(mmHg)	(mmHg)	(ml/kg/min)
Recovery			
+1	REC1_SPAP	REC1_DPAP	REC1_VO2
+2	REC2_SPAP	REC2_DPAP	REC2_VO2
+3	REC3_SPAP	REC3_DPAP	REC3_VO2
+4	REC4_SPAP	REC4_DPAP	REC4_VO2
+5	REC5_SPAP	REC5_DPAP	REC5_VO2
Peak			
___ : ___ minutes : seconds	PEAK_SPAP	PEAK_DPAP	PEAK_VO2

PEAK_TIME_MIN

PEAK_TIME_SEC

5. Was hemoglobin measured at peak exercise (0=No, 1=Yes) ..... HGB_MEAS ___
   a. Measured hemoglobin at peak exercise (g/dl) ..... HGB ..... ___.___
   b. Where was blood taken for hemoglobin? (1=Peripheral blood, 2=PA blood sample) ..... HGB_LOC ___

6. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form ..... ___ ___ PHYS_REVIEW
   (Note: *username of physician is the first 6 letters of last name and first initial.)*

7. Are any comments documented? (0=No comments, 1=Yes, specify below) ..... COMMENTS_DOC ___

Comments: COMMENTS

200. Date form completed (mm/dd/yyyy) ..... ___ ___/___ ___/ COMP_DT

201. Username of person completing/reviewing completeness of this form ..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT

Username of person entering this form ENTER_USER

PVD_CPET_RESULTS

PVDOMICS

PVDOMICS STUDY
CPC Cardiopulmonary
Exercise Test (CPET) Results Form #292

Instructions: This form is for use by the staff at the Cardiovascular Physiology Core (CPC) when reviewing center CPET results.

PID	AC	VISIT_DT
1. Identification Number	2. Alphacode	3. Date of CPET (mm/dd/yyyy)

4. Is CPET acceptable quality? ..... QUALITY .....

0 = Unacceptable, no usable data: no data will be entered. The Core has checked with the site and verified that usable data is not available. *(skip to Q200)*

1 = Unacceptable, missing several key pieces of data: some data will be entered but the form will not be completely filled in. The Core has checked with the site and verified that no other data is available.

2 = Yes, acceptable: the majority of the data was collected and it was accurate and collected per protocol.

CPET Measurements - Complete Items Q6-9, a-j for both non-invasive CPET and invasive CPET (iCPET). ***Continue with Items Q10-13, a-f on next page for iCPET only.***

Submaximal is measured at 2 minutes of exercise. Recovery is measured at 2 minutes post exercise and at the last available time point post exercise that is greater than 2 minutes.

REC_HR_MIN

	5. At Rest	6. Submaximal (2 min of exercise)	7. At Peak Exercise	8. Recovery (2 min post exercise)	§	9. Recovery (last available post exercise >2 min)
a. Heart Rate (bpm)	REST_HR	SUB_HR	PEAK_HR	REC2_HR		REC_HR
b. Blood Pressure (mmHg) (systolic/diastolic)	REST_BP_SYS REST_BP_DIA	SUB_BP_SYS SUB_BP_DIA	PEAK_BP_SYS PEAK_BP_DIA	REC2_BP_SYS REC2_BP_DIA	REC_BP_SYS_MIN REC_BP_DIA_MIN	REC_BP_SYS REC_BP_DIA
c. Oxygen Saturation (%)	REST_O2_SAT	SUB_O2_SAT	PEAK_O2_SAT	REC2_O2_SAT	REC_O2_SAT_MIN	REC_O2_SAT
d. Respiratory Rate	REST_RESP_RATE	SUB_RESP_RATE	PEAK_RESP_RATE	REC2_RESP_RATE	REC_RESP_RATE_MIN	REC_RESP_RATE
e. VO_2 (ml/kg/min)	REST_VO2	SUB_VO2	PEAK_VO2	REC2_VO2	REC_VO2_MIN	REC_VO2
f. VCO_2 (ml/kg/min)	REST_VCO2	SUB_VCO2	PEAK_VCO2	REC2_VCO2	REC_VCO2_MIN	REC_VCO2
g. Respiratory Exchange Ratio (RER)*	REST_RER	SUB_RER	PEAK_RER	REC2_RER	REC_RER_MIN	REC_RER
h. V_E (BTPS) (L/min)	REST_VE	SUB_VE	PEAK_VE	REC2_VE	REC_VE_MIN	REC_VE
i. Tidal Volume (V_T) (mL)	REST_TIDAL	SUB_TIDAL	PEAK_TIDAL	REC2_TIDAL	REC_TIDAL_MIN	REC_TIDAL

§ = last available time point code: 2:30min=1; 3min=2; 3:30min=3; 4min=4; 4:30min=5; 5min=6

*RER = VCO_2/VO_2

Record Invasive CPET measures in Q10-13, k-o below (if applicable).

Submaximal is measured at 2 minutes of exercise. Recovery is measured at 2 minutes & 5 minutes post exercise.

Continue, if invasive	**10. At Rest**	**11. Submaximal** (2 min of exercise)	**12. At Peak Exercise**	**13. Recovery** (2 min post exercise)	**14. Recovery** (5 min post exercise)
a. RA Pressure (RAP)	REST_RAP	SUB_RAP	PEAK_RAP	REC2_RAP	REC_RAP
b. Mean PA Pressure (mPAP)	REST_MPAP	SUB_MPAP	PEAK_MPAP	REC2_MPAP	REC_MPAP
c. Systolic PA Pressure (sPAP)	REST_SPAP	SUB_SPAP	PEAK_SPAP	REC2_SPAP	REC_SPAP
d. Diastolic PA Pressure (dPAP)	REST_DPAP	SUB_DPAP	PEAK_DPAP	REC2_DPAP	REC_DPAP
e. Pulmonary Capillary Wedge Pressure	REST_PCW	SUB_PCW	PEAK_PCW	REC2_PCW	REC_PCW
f. Direct Fick Cardiac Output (L/min)	REST_DFCO	SUB_DFCO	PEAK_DFCO	REC2_DFCO	REC_DFCO

CPET TEST RESULTS:

15. Maximum watts achieved ..... MAX_WATTS
16. Exercise duration (minutes)..... EXER_DUR_MIN EXER_DUR_SEC
17. Did RER reach or exceed 1.10? (0=No, 1=Yes)..... RER_REACH_EXCEED
18. Percent predicted VO_2 max (%)..... VO2_MAX _ _ _
19. Maximum METS achieved (Functional capacity)* ..... METS_MAX _ _ . _

Comments: COMMENTS

199. Username of physician reading the CPET and filling out this form..... PHYS_READ
(Username of physician is the first 6 letters of last name and first initial.)

200. Date form completed (mm/dd/yyyy) ..... _ _/_ _/ COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT

Username of person entering this form _ _ ENTER_USER

*If not provided, calculate METS as Peak VO_2/3.5

PVDOMICS

PVDOMICS STUDY
Event(s) Notification Form #400

Instructions: This form is completed as soon as the Clinical Center identifies that a participant event has occurred. An event can be an adverse event (AE) and/or serious adverse event (SAE) such as but not limited to: life threatening condition, hospitalization, death or other event. Events that occur during the study period or within 2 weeks of study completion should be reported. The timeline and procedures for AE/SAE reporting follow the guidelines by PVDOMICS OSMB and NHLBI Adverse Event and Unanticipated Problem Reporting Policy.

Events Reporting Timelines

Event	Report on Form		Phone call and e-mail to DCC co-PIs [1]	Report to Local IRB as required	Auto e-mail sent to :	
	400 (report immediately upon learning of the event)	401			400	401
Any SAE within 24 hours of study procedure (regardless of relatedness or expectedness) [2]	X	X (within 1 week of learning of the event)	X	X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
A) Any death [2] OR B) Life-threatening SAE that is: - possibly, probably or definitely related to a study procedure AND - unexpected or expected, but of greater severity than described in consent [2]	X	X (within 1 week of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
Non-fatal, non-life-threatening SAE or unanticipated adverse event that is: - possibly, probably or definitely related to a study procedure AND - unexpected or expected, but of greater severity than described in consent	X	X (within 2 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC NHLBI OSMB Chair
Non-fatal event that happened more than 24 hours after study procedure and is: - not related or unlikely to be related to a study procedure OR - possibly, probably or definitely related to a study procedure but is expected and accurately described in the consent	X	X (within 4 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC

[1] For SAEs within 24 hours of study procedure:
The clinical center PI must notify the DCC **immediately** upon learning about the event as follows:
- Call one of the DCC co-PIs [Dr. Beck at (216) 444-9927 or Dr. Erzurum at (216) 312-3116] AND
- Send an e-mail to both Drs. Beck and Erzurum (beckg@ccf.org, erzurus@ccf.org). Be sure to use the option in your e-mail software that requests a delivery receipt.

[2] These classes of safety events are subject to expedited reporting to NHLBI and the OSMB. All other safety events are reported to NHLBI and the OSMB as part of routine reports.

PVD_EVENT_NOTIF

PVDOMICS

PVDOMICS STUDY
Event(s) Notification Form #400

PID | AC | VISIT_DT

1. Identification Number | 2. Alphacode | 3. Date center first heard of event: mm/dd/yyyy

Type of event that occurred:

4. Death (0=No, 1=Yes, requires expedited reporting) ..... DTH_EVENT
   a. Date of death (mm/dd/yyyy) ..... DTH_DT
   b. Occurred within 24 hours of a study procedure? (0=No, 1=Yes) ..... DTH_24HR
5. Hospitalization (0=No, 1=Yes) ..... HOSP_EVENT
   a. Date of admission (mm/dd/yyyy) ..... HOSP_DT
   b. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting) ..... HOSP_24HR
6. Life-threatening event (0=No, 1=Yes) ..... LIFE_THRT_EVENT
   a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting) ..... LIFE_THRT_24HR
7. Prolonged hospitalization (0=No, 1=Yes) ..... PROLONG_EVENT
   a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting) ..... PROLONG_24HR
8. Other SAE (0=No, 1=Yes) ..... SAE_EVENT

   Note: Event that occurred during hospitalization that in itself would have triggered a hospitalization, lead to persistent disability, congenital abnormality, or inability to conduct normal life functions

   a. Occurred within 24 hours of a study procedure? (0=No, 1=Yes – requires expedited reporting) ..... SAE_24HR
9. Was this an adverse event only (0=No, 1=Yes) ..... AE_ONLY
10. a. In the Clinical Center Physician's judgment*, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol? ..... CAUSE_PROC_DEV
    (0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)

    b. If the event was possibly, probably, or definitely caused by any procedure or device, done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? DESCR_CONSENT
    1=Unexpected – not mentioned in the consent
    2=Expected, but of greater severity than mentioned in the consent
    3=Expected and accurately described in the consent

* *Judgment questions in 10a & b are repeated on Form 401. Only Form 401 responses will be used for reporting purposes. Documents that help with determining judgment should be submitted using Form 402 when requested by the DCC.*

11. Provide a brief comment in the box below concerning event(s) that occurred: COMMENTS

200. Date form completed (mm/dd/yyyy) ..... COMP_DT

201. Username of person completing/reviewing completeness of this form..... COMP_USER

202. Username of physician reviewing accuracy and completeness of this form ..... PHYS_REVIEWER

(Username is the first 6 letters of physician's last name and first initial.)

Clinical Center Use Only

Date form entered (mm/dd/yyyy) _ _/_ _/ ENTER_DT

Username of person entering this form _ _ ENTER_USER

PVDOMICS

PVDOMICS STUDY
Detailed Serious Adverse/Adverse Event Form #401

Instructions: See page 2 for detailed instructions on form completion.

Events Reporting Timelines

Event	Report on Form		Phone call and e-mail to DCC co-PIs [1]	Report to Local IRB as required	Auto e-mail sent to :	
	400 (report immediately upon learning of the event)	401			400	401
Any SAE within 24 hours of study procedure (regardless of relatedness or expectedness) [2]	X	X (within 1 week of learning of the event)	X	X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
A) Any death [2] OR B) Life-threatening SAE that is: - possibly, probably or definitely related to a study procedure AND - unexpected or expected, but of greater severity than described in consent [2]	X	X (within 1 week of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
Non-fatal, non-life-threatening SAE or unanticipated adverse event that is: - possibly, probably or definitely related to a study procedure AND - unexpected or expected, but of greater severity than described in consent	X	X (within 2 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC NHLBI OSMB Chair
Non-fatal event that happened more than 24 hours after study procedure and is: - not related or unlikely to be related to a study procedure OR - possibly, probably or definitely related to a study procedure but is expected and accurately described in the consent	X	X (within 4 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC

[1] For SAEs within 24 hours of study procedure:
The clinical center PI must notify the DCC **immediately** upon learning about the event as follows:
- Call one of the DCC co-PIs [Dr. Beck at (216) 444-9927 or Dr. Erzurum at (216) 312-3116] AND
- Send an e-mail to both Drs. Beck and Erzurum (beckg@ccf.org, erzurus@ccf.org). Be sure to use the option in your e-mail software that requests a delivery receipt.

[2] These classes of safety events are subject to expedited reporting to NHLBI and the OSMB. All other safety events are reported to NHLBI and the OSMB as part of routine reports.

Instructions: This form is completed as soon as the Clinical Center identifies that a participant event has occurred. An event can be an adverse event (AE) and/or serious adverse event (SAE) such as but not limited to: life threatening condition, hospitalization, death or other event. Refer to MOP for details on AEs and SAEs. Events that occur during the study period or within 2 weeks of study completion should be reported. The timeline and procedures for AE/SAE reporting follow the guidelines by PVDOMICS OSMB and NHLBI Adverse Event and Unanticipated Problem Reporting Policy. Enter this form with the available information within the timeline. Add further details and final outcome later if not available at the time. The form is considered incomplete until the final outcome information is provided.

It is up to the physician's clinical judgment to decide when an adverse event (SAE or AE) has occurred. Enter this adverse event form when the Clinical Center Study Team (Physician and Study Coordinator) feels that the participant has had an event (such as, a sign, symptom or disease) that the Study Team feels is important to document for the PVDOMICS Study. For SAE's, AE's, review and complete each main section question*.

This form should be entered following the deadlines in the table above with as much information as available at the time. You will be able to go back and **update the form as many times as needed until the final outcome is available**. Once you enter the final outcome (i.e., Q22a is not *6=Not available yet*), the form will be considered final and any further changes will need to go through the inquiry system.

PVDOMICS

PVDOMICS STUDY
Detailed Serious Adverse/Adverse Event Form #401

1. Identification Number **PID** | 2. Alphacode **AC** | 3. Date center first heard of event (mm/dd/yyyy) **VISIT_DT**

4. Date of event onset (mm/dd/yyyy)..... **ONSET_DT** ___ ___/___ ___/___ ___ ___ ___

DEATH

5. Did the participant die? (0=No-skip to Q8, 1=Yes) ..... **DEATH** ___

Detailed documentation regarding the participant's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) should be submitted to the DCC when requested.

6. a. Date of death (mm/dd/yyyy)..... **DEATH_DT** ___ ___/___ ___/___ ___ ___ ___

b. Did this death occur within 24 hours of study procedure (0=No, 1=Yes)..... **DEATH_24HR** ___

c. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol? (0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)..... **DEATH_PVD_CAUSED** ___

d. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? ..... **DEATH_EXPECTED** ___

1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

e. Where did the death occur? ..... **DEATH_LOC** ___

1=In a hospital, in the emergency room
2=In a hospital, not in the emergency room
3=In the participant's home
4=In a nursing home or other skilled care facility
9=Location unknown
(Contact the DCC if another code is needed)

f. Was an autopsy performed? (0=No, 1=Yes, 9=unknown) ..... **AUTOPSY** ___

If YES, be sure to include the autopsy report in the documentation.

The list of cause(s) of death needs to be completed by the Principal Investigator:

	Cause(s) of Death (*Note: A procedure code cannot be a primary cause of death.*)	**MedDRA** ***Auto-populated***
7a. Primary Cause:	**PRIM_COD**	**PRIM_COD_MEDDRA**
7b. Secondary Cause:	**SEC_COD**	**SEC_COD_MEDDRA**
7c. Additional Cause:	**ADD1_COD**	**ADD1_COD_MEDDRA**
7d. Additional Cause:	**ADD2_COD**	**ADD2_COD_MEDDRA**
7e. Additional Cause:	**ADD3_COD**	**ADD3_COD_MEDDRA**

HOSPITALIZATION:

8. Was there an in-patient hospitalization? (0=No, skip to Q16, 1=Yes) ..... **HOSP** ___

   a. Date of hospital admission (mm/dd/yyyy) ..... **ADMIT_DT** ___ ___ /___ ___ /___ ___ ___ ___

   b. Did this hospitalization occur within 24 hours of study procedure (0=No, 1=Yes)..... **HOSP_24HR** ___

   c. Was this a planned hospitalization (0=No, 1=Yes, 9=Unknown)..... **HOSP_PLANNED** ___

   d. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol? (0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)..... **HOSP_PVD_CAUSED** ___

   e. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? ..... **HOSP_EXPECTED** ___

   1=Unexpected – not mentioned in the consent
   2=Expected, but of greater severity than mentioned in the consent
   3=Expected and accurately described in the consent

The list of causes needs to be completed by the Principal Investigator:

	Cause(s) of Hospital Admission – (*Note: A procedure code cannot be a primary cause of hospitalization)*	**MedDRA** ***Auto-populated***
9a. Primary Cause:	**PROM_HOSP**	**PRIM_HOSP_MEDDRA**
9b. Secondary Cause:	**SEC_HOSP**	**SEC_HOSP_MEDDRA**
9c. Additional Cause:	**ADD1_HOSP**	**ADD1_HOSP_MEDDRA**
9d. Additional Cause:	**ADD2_HOSP**	**ADD2_HOSP_MEDDRA**
9e. Additional Cause:	**ADD4_HOSP**	**ADD3_HOSP_MEDDRA**
9f. Additional Cause:	**ADD4_HOSP**	**ADD4_HOSP_MEDDRA**

10. Did the participant have a surgical procedure done during this hospitalization? (0=No, 1=Yes) ..... ___

	Type of Procedure(s) Performed While in Hospital	**MedDRA** ***Auto-populated***
10a.Procedure 1	**HOSP_PROC1**	**HOSP_PROC1_MEDDRA**
10b.Procedure 2	**HOSP_PROC2**	**HOSP_PROC2_MEDDRA**
10c.Procedure 3	**HOSP_PROC3**	**HOSP_PROC3_MEDDRA**
10d.Procedure 4	**HOSP_PROC4**	**HOSP_PROC4_MEDDRA**

11. a. Did the participant receive a functioning transplant during this hospitalization? (0=No, 1=Yes) . **TRANS** ___

   b. If Q11a = 1, type of transplant received?..... **TRANS_TYPE** ___

   1=Single-lung transplant
   2=Double-lung transplant
   3=Heart tranplant
   4=Heart-lung transplant
   5=Other transplant

12. Was there prolongation of existing hospitalization? (0=No, 1=Yes) ..... **PROLONG_HOSP** ___

a. Did this event occur within 24 hours of study procedure (0=No, 1=Yes) ..... **PROLONG_HOSP_24HR** ___

b. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol? (0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)..... **PROLONG_HOSP_PVD_CAUSED** ___

c. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? ..... **PROLONG_HOSP_EXPECTED** ___

1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

The list of causes needs to be completed by the Principal Investigator:

	Cause(s) of Prolongation of Hospitalization	MedDRA *Auto-populated*
13a. Primary Cause:	**PRIM_PROLONG**	**PRIM_PROLONG_MEDDRA**
13b. Secondary Cause:	**SEC_PROLONG**	**SEC_PROLONG_MEDDRA**
13c. Additional Cause:	**ADD1_PROLONG**	**ADD1_PROLONG_MEDDRA**
13d. Additional Cause:	**ADD2_PROLONG**	**ADD2_PROLONG_MEDDRA**
13e. Additional Cause:	**ADD3_PROLONG**	**ADD3_PROLONG_MEDDRA**

14. Did this hospitalization result in a persistent or significant incapacity? (0=No, 1=Yes) ..... **HOSP_INCAPACITY** ___

15. a. Status of participant at the end of hospitalization..... **HOSP_PT_STATUS** ___
1=Discharged to home
2=Discharged to be admitted to rehab, a nursing home or other facility
3=Died
4=Still in hospital (*only use this option if several weeks have elapsed*)

b. If Q15a = 1 or 2, date of discharge (mm/dd/yyyy) ..... **DISCH_DT** ___ ___ /___ ___ /___ ___ ___ ___

Note: If the participant is still in the hospital (Q15a=4) at the time of the initial completion of the form, Q15a-b need to be updated when this information becomes available.

LIFE-THREATENING EVENT

16. Did the participant experience a life threatening event? (0=No, 1=Yes) ..... **LIFE_THREAT** ___

a. Did this life-threatening event occur within 24 hours of study procedure (0=No, 1=Yes)..... **LIFE_THREAT_24HR** ___

b. Did this life threatening event require treatment (0=No, 1=Yes)..... **LIFE_THREAT_TREATMENT** ___

c. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol? (0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)..... **LIFE_THREAT_PVD_CAUSED** ___

d. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? ..... **LIFE_THREAT_EXPECTED** ___

1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

The list of life-threatening cause(s) needs to be completed by the Principal Investigator:

	Life-Threatening Cause(s)	MedDRA *Auto-populated*
17a. Cause 1:	**PRIM_LIFE_THREAT**	**PRIM_LIFE_THREAT_MEDDRA**
17b. Cause 2:	**SEC_LIFE_THREAT**	**SEC_LIFE_THREAT_MEDDRA**
17c. Cause 3:	**ADD1_LIFE_THREAT**	**ADD1_LIFE_THREAT_MEDDRA**
17d. Cause 4:	**ADD2_LIFE_THREAT**	**ADD2_LIFE_THREAT_MEDDRA**
17e. Cause 5:	**ADD3_LIFE_THREAT**	**ADD3_LIFE_THREAT_MEDDRA**

18. Did the life-threatening event result in a persistent or significant incapacity? (0=No, 1=Yes) .....___
LIFE_THREAT_INCAPACITY

OTHER EMERGENCY DEPARTMENT VISIT AND SAE/AE

19. Did participant have an **Emergency Department** visit? (0=No, 1=Yes, complete below) .....___
ER_VISIT

a. Did this ED visit occur within 24 hours of study procedure (0=No, 1=Yes) ..... ___
ER_24HRS

b. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely).....___
ER_CAUSED

c. If the event was possibly, probably, or definitely caused by any procedure or device that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? .....___
ER_EXPECTED
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

	Condition(s)-Enter signs/symptoms/condition description(s) that triggered the ER visit - *(database will allow as many conditions as needed)*	MedDRA *Auto-populated*
19c. Condition 1:	**EVENT_DESC**	**EVENT_DESC_MEDDRA**
19d. Condition 2:		
19e. Condition 3:		
19f. Condition 4:		
19g. Condition 5:		

Continued on next page

20. In the opinion of the physician, was/were there other diagnoses and/or signs and/or symptoms <u>not previously documented</u> that are important to document for the PVDOMICS Study (0=No, 1=Yes, complete below) ..... **OTH_EVENT** ___

If SAE,for column labeled '**If SAE, Study Caused**?':
In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)

For column labeled '**If SAE, Expected**?' Use the following response codes:
If the event was possibly, probably, or definitely caused by any procedure or device that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent?
1=Unexpected – not mentioned in the consent,
2=Expected, but of greater severity than mentioned in the consent,
3=Expected and accurately described in the consent

	Condition(s)-Enter signs/symptoms/condition description(s) *(database will allow as many conditions as needed)*	**MedDRA** ***Auto-populated***	**AE/SAE? 1=AE only 2=SAE, < 24 hrs of PVD test 3=SAE, >24 hrs of PVD test**	**If SAE, Study Caused?**	**If SAE, Expected?**
20a. Condition 1:	**EVENT_DESC**	**EVENT_DESC_MEDDRA**	___	___	___
20b. Condition 2:			**AE_SAE**	**AE_SAE_CAUSED** ___	___
20c. Condition 3:			___	___	**AE_SAE_EXPECTED** ___
20d. Condition 4:			___	___	___
20e. Condition 5:			___	___	___

21. Did participant have an outpatient surgical procedure done? (0=No, 1=Yes, complete below) ..... **OP_SURG** ___

	Cause(s) for which Procedure(s) Performed as an Outpatient	**MedDRA** ***Auto-populated***
21a.Cause 1	**OP_COND1**	**OP_COND1_MEDDRA**
21b.Cause 2	**OP_COND2**	**OP_COND_MEDDRA2**

	Type of Procedure(s) Performed as an Outpatient	**MedDRA** ***Auto-populated***
21c.Procedure 1	**OP_SURG1**	**OP_SURG1_MEDDRA**
21d.Procedure 2	**OP_SURG2**	**OP_SURG2_MEDDRA**

22. a. Final outcome of event ..... **OUTCOME** ___
0=Recovered without treatment
1=Recovered with treatment
2=Event continuing without treatment (if continues, use same date as Q200-date form completed)
3=Event continuing and controlled with treatment (if continues, use same date as Q200-date form completed)
4=Event continuing and not controlled with treatment (if continues, use same date as Q200-date form completed)
5=Participant died
6=Not yet available

22. b. Date of final outcome (mm/dd/yyyy) ..... **OUTCOME_DT** ___ ___/___ ___/___ ___ ___ ___

If Q22a=6 at time of the initial form completion, Q22a and Q22b need to be updated when the final outcome information is available. Once you enter the final outcome (i.e., Q22a is not 6=Not available yet), the form will be considered final and any further changes will need to go through the inquiry system.

23. Please write a summary of what happened, what action was taken and final outcome.

EVENT_SUMMARY

200. Date form completed (mm/dd/yyyy) ..... ___ ___/___ ___/___ ___ ___ ___

201. Username of PVDOMICS Study staff member completing this form..... ___ ___ ___ ___ ___ ___ ___

202. Username of physician reviewing accuracy and completeness of this form..... ___ ___ ___ ___ ___ ___ ___

(*Username is the first 6 letters of physician's last name and first initial.)*

Clinical Center Use Only

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

Username of person entering this form___ ___ ___ ___ ___ ___ ___

The Data Coordinating Center (DCC) will notify clinical center staff to complete and enter Form 402 when an event (hospitalization, ER visit, other SAE and/or death) shows that a packet needs to be <u>scanned and uploaded to DCC secure portal.</u> See the MOP for detailed instructions on processing the packet.

Form 401 updates. 07/10/2019-Per OSMB, expectedness and relatedness added to Q19 and Q20. 07/13/2018: Numbering updated starting at Q17; more lines added to Comments section. 10/03/2018: Use of MedDRA coding implemented due to multiple versions of ICD10 codes.

PVDOMICS

PVDOMICS STUDY and L-PVDOMICS STUDY
COVID-19 Vaccination Details Form #900

Instructions: This form captures COVID-19 vaccination information about participants from both the parent PVDOMICS Study and those participating in L-PVDOMICS Study.

Enter this form when a study participant received a COVID-19 vaccination as soon as identified. Like the Form 10, you will be able to query up and update this form whenever new information needs to be added.

Important: Continue to follow COVID-19 vaccination status periodically in order to capture all vaccination and booster information.

PID | **AC** | **VISIT_DT**

1. Identification Number | 2. Alphacode | 3. Date of initial COVID-19 vaccine review (mm/dd/yyyy)

COVID-19 Vaccination Questions

5. At the time of this review, has the participant received a vaccination for COVID-19? **VACCINE_1** ____

1=No, participant contacted and vaccination not received, still thinking about it (proceed to Q200)
2=No, participant contacted and refuses vaccine (proceed to Q200)
3=No, not yet but participant is planning on getting vaccinated (proceed to Q200)
4=Yes, received vaccination / booster (proceed to Q5a)
8=Participant refuses to provide vaccination status (proceed to Q200)
9=Unknown: information not recorded in electronic health record, participant was not contacted

Note: *for dates in Q5a and Q6a, record date as best as participant can remember. If day is missing, enter '15' in the database.*

a. When was first dose given? (mm/dd/yyyy) **VACCINE_1_DT** ___ ___/___ ___/___ ___ ___ ___

b. What was the name of the manufacturer of the vaccine? **VACCINE_1_MANUF** ____

1=Pfizer/BioNTech (2 doses)
2=Moderna (2 doses)
3=Janssen/Johnson & Johnson
4=AstraZeneca (*aka Vaxzevria and Covishield*)
5=Sputnik V/Sputnik Light
6=Comirnaty
7=Coronovac/Sinovac
8=Other
9=Unknown

6. Was a second dose given? **VACCINE_2** ____

0=No, second dose scheduled but not yet received (skip to Q7)
1=No, participant refused the second vaccine dose (skip to Q7)
2=Yes, second dose received (complete Q6a-b)
8=N/A, only 1 dose expected (skip to Q7)

a. When was second dose given? (mm/dd/yyyy) **VACCINE_2_DT** ___ ___/___ ___/___ ___ ___ ___

b. What was the name of the manufacturer of the vaccine? **VACCINE_2_MANUF** ____

1=Pfizer/BioNTech (2 doses)
2=Moderna (2 doses)
3=Janssen/Johnson & Johnson
4=AstraZeneca (*aka Vaxzevria and Covishield*)
5=Sputnik V/Sputnik Light
6=Comirnaty
7=Coronovac/Sinovac
8=Other
9=Unknown

BOOSTER DOSE

7. At the time of this review, has the participant received a **BOOSTER** dose for COVID-19? **BOOSTER** ____

1=No, participant contacted and booster vaccination not received, still thinking about it (proceed to Q200)
2=No, participant contacted and refuses booster vaccine (proceed to Q200)
3=No, not yet but participant is planning on getting booster (proceed to Q200)
4=Yes, received booster vaccination (Complete Q7a-b)
8=Participant refuses to provide vaccine booster status (proceed to Q200)
9=Unknown, information not recorded in electronic health record, participant was not contacted

Note: *for dates in Q7a, record date as best as participant can remember. If day missing, enter '15' in the database..*

a. When was **booster** dose given? (mm/dd/yyyy)..... **BOOSTER_DT** ___ ___/___ ___/___ ___ ___ ___

b. What was the name of the manufacturer of the **booster** dose? ..... **BOOSTER_MANUF** ___

1=Pfizer/BioNTech
2=Moderna
3=Janssen/Johnson & Johnson
4=AstraZeneca (*aka Vaxzevria and Covishield*)
5=Sputnik V/Sputnik Light
6=Comirnaty
7=Coronovac/Sinovac
8=Other
9=Unknown

8. Comments: **COMMENTS** _____

_____

_____

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___ ___ ___ ___ ___ ___ ___