

PVDOMICS Study - Central Training
Cleveland Clinic
November 7-8, 2016 Final

Agenda

DAY 1 – Monday, November 7, 2016 – Lerner Research Institute NA1-138

7:45 a.m.	Meet in Holiday Inn lobby to be guided to LRI meeting room	Ms. Matuska
8:00 a.m.	Welcome and Introductions	Dr. Beck
8:05 a.m.	NHLBI Opening Comments.....	Dr. Xiao
8:10 a.m.	Organizational Structure 1. Clinical centers 2. DCC 3. Clinical Cores 4. Biorepository Core • Omics Core	Dr. Beck
8:15 a.m.	Introduction to the Study 1. Background for the study and overview of PH 2. Study goals 3. Study timeline • Planning • Recruitment • Follow-up • Analyses and Publications 4. Enrollment targets 5. Participant timeline • Screening • Consent • Study visits (up to 6 weeks) • Follow-up (vital status)	Drs. Highland, Beck
8:30 a.m.	Clinical Center Documentation and Its Personnel/Equipment 1. Clinical Center Data (<i>Form 09</i>) • All Clinical Centers require IRB Approval 2. Clinical Center Study Personnel (<i>Form 10</i>) • Ready to enroll at center will require at least one PI, one study coordinator and lab tech person • Use to notify DCC if someone leaves your center or a new person is hired • Check your center's page in the Address Directory 3. Clinical Center Equipment (<i>Form 20</i>)	Ms. Sherer

8:35 a.m.	Recruitment and Consenting Participants..... <i>See Manual of Operations, Chapters 4 and 30)</i> 1. Recruiting patients • Finding patients from PH clinics • Websites • Other methods: Giving Grand Rounds/posters/brochures 2. Determining general eligibility of participants (<i>Form 101</i>) 3. PVD assessment (<i>Forms 102-103</i>) 4. Types of consent needed for this study • Study consent required for all • Biobank consent optional 5. When to consent patients 6. How to consent patients • Consent process • Genetic testing and reporting individual findings to centers • Biobank consent and use of stored biospecimens • GUID number 8. Incidental Findings 9. Collecting participant personal and contact information 10. Reasons for participants not being approached or consented	Dr. Highland, Ms. Sherer and Study Coordinators
9:00 a.m.	Adjudication Committee Process 1. Determining WHO Group assignment (<i>Form 102</i>)	Drs. Highland, Beck
9:10 a.m.	Initial Forms..... <i>(Basic forms not related to special study procedures)</i> 1. <i>Form 100</i> Initial Enrollment 2. <i>Forms 104-107</i> Other Assessments 3. Health-related Quality of Life Questionnaires (<i>Forms 170-172</i>)	Ms. Sherer, Dr. Highland
9:30 a.m.	Medications Reporting (<i>Form 110</i>) and Events 1. Event(s) Notification (<i>Form 400</i>) 2. Event(s) Details (<i>Form 401</i>) • AE's • SAE's (SAEs, Hospitalizations, Deaths) 3. Submitting supporting documentation (<i>Form 402</i>)	Dr. Highland, Ms. Sherer
10:00 a.m.	Break	
10:15 a.m.	Cardiac Imaging Core..... 1. MRI (<i>Form 250</i>) 2. Echo (<i>Form 251</i>)	Ms. Flinn, Park, Kassimatis
10:45 a.m.	Lung Imaging Core..... 1. Lung CT (<i>Forms 252, 253</i>) 2. V/Q (<i>Forms 254, 255</i>)	Dr. Lempel
11:15 a.m.	Sleep Study Core..... 1. Clinical Center research sleep study (<i>Forms 150, 151, 152</i>)	Dr. Mehra, Ms. Nawabit

2. Historical sleep studies (*Forms 155*)

12:15 p.m. Lunch

1:00 p.m. Biorepository Core..... Dr. Comhair, Ms. Peterson
1. Blood Collection 1 (*Forms 300-303*)
2. Urine Collection (*Forms 320, 321*)

1:30 p.m. Cardiac Physiology Core..... Ms. Kirsop, Drs. Tang, Comhair, Ms. Peterson
1. RHC (includes blood collection 2 - *Forms 280, 304-309*)
2. ECG (*Form 245*)
3. CPET (*Forms 290, 291*)

3:00 p.m. Break

3:15 p.m. Clinical Measurements..... Ms. Matuska, Ms. Block, Ms. McNallan
1. Vital signs (*Form 120*)
2. Waist-Hip measurement (*Form 131*)
3. Bioelectrical Impedance (BIA) (*Form 132*)

3:45 p.m. Lung Physiology Core..... Dr. Olman
1. Spirometry, DLCO, Plethysmography (*Form 270*)
2. Historical PFTs (*Form 271*)
3. 6 Minute Walk (*Form 133*)

4:30 p.m. Scheduling Participant Visits Dr. Erzurum, Ms. Sharp

5:00 p.m. Adjourn

6:30 p.m. Group Dinner at Michaelangelo's
2198 Murray Hill Rd, Cleveland, OH 44106 mangelos.com

DAY 2 – Tuesday, November 8 – MM1-106 and 107

7:45 a.m. Meet in Holiday Inn lobby to be guided to computer room Ms. Collart

Training Session for Hands-on Computer Training
Data entry – Online look-up tables – Online data discrepancy resolution

8:00 a.m. Study Web Page DCC Systems Group
1. Webpage (<http://qhsapps.ccf.org/pvdomics/>)
 o Public and password protected documents
2. Database accounts
 o Who needs, how to get, never share
3. Passwords

8:15 a.m.	Collecting Quality Research Data	Ms. Sherer, Ms. Collart
	1. How to fill out paper forms 2. Data changes on the paper forms 3. Print out screens if you enter data directly online – Keep a paper record 4. Source documentation and storage	
8:30 a.m.	How to Enter Forms	DCC Systems Group
	1. Data entry overview 2. Assigning participant ID numbers (<i>Form 100</i>) 3. How to identify drugs using WHODrug look-up table (<i>Form 110</i>)	
9:15 a.m.	Data Discrepancy Resolution.....	DCC Systems Group
	1. How to look at previously entered data 2. Early data changes (within 7 days) 3. Late data changes (more than 7 days) 4. How to respond to data discrepancy inquiries	
10:00 a.m.	Practice	Centers, DCC Systems Group
	1. Forms data entry: Center Form 10, Participant Form 100, Medications Form 110 2. Inquiries – includes early data changes (within 7 days), pull up a previously entered form, change data, make a change data request and respond to an inquiry	
11:00 a.m.	Break	
11:20 a.m.	SSH Data/File Transfer.....	DCC Systems Group
11:40 a.m.	Future Issues.....	Dr. Beck
	• Tasks to be accomplished before participant enrollment begins	
12:00 p.m.	Items to Refer to the Steering Committee for Resolution.....	Dr. Beck
12:15 p.m.	Review: Questions and Answers	
1:00 p.m.	Adjourn	