

Agenda 02/28/2018

PVDOMICS Study – Central Training Cleveland Clinic Thursday, March 1st, 2018

Brittany Matuska to pick up trainees from the Holiday Inn lobby and walk to training room

(Leave your bags with the bell captain)

THURSDAY, MARCH 1, 2018 - *Lerner Research Institute, NA2-17*

- 7:40 a.m. Meet in Hotel lobby to be guided to LRI meeting room.....Ms. Matuska**
- 8:00 a.m. Welcome and Introductions Dr. Beck**
1. PVDOMICS Organization chart
- 8:05 a.m. Brief Overview of PVDOMICS Dr. Highland**
1. Background and purpose
 2. Protocol
 3. Study Coordinator role
 4. Study timeline
 5. Participant timeline
 - Screening
 - Consent
 - Study visits (up to 6 weeks)
 - Follow-up (vital status)
 - Extensions/Exceptions/[Dropouts]
- 8:15 a.m. Clinical Center Documentation Ms. Sherer**
1. Clinical Center Study Personnel (*Form 10*)
 - Personnel updates
 - Study web page
 - Address Directory
 - Database account/Secure portal accounts
- 8:20 a.m. Recruitment and Consenting Participants Dr. Highland**
- See Manual of Operations, Chapter 4*
1. Target enrollment
 2. Recruitment strategies
 3. Determining general eligibility of participants (*Form 100*)
 - Must work closely with PI/Clinicians familiar with PVDOMICS Protocol for selecting appropriate individuals to approach for participation
 4. Types of consent needed for this study
 - Study consent required for all
 - Biobank consent *optional*
 - Submission of de-identified signature pages
 5. When to consent patients
 6. Collecting participant personal and contact information
 7. Incidental findings

- 8:35 a.m. Scheduling Participant Visits.....Dr. Highland & Ms. Sharp**
- 8:40 a.m. General Forms Overview Ms. Sharp**
(Forms not related to special study procedures)
1. *Form 100* Initial Enrollment
 2. *Forms 104-107* Other Assessments
 3. Medications Reporting (*Form 110*)
 4. Health-related Quality of Life Questionnaires (*Forms 170-172*)
- 8:50 p.m. Clinical Measurements Ms. Sharp**
1. Vital signs (*Form 120*)
 2. Waist-Hip measurement (*Form 131*)
 3. Bioelectrical Impedance (BIA) (*Form 132*)
- 9:00 a.m. PVDOMICS Assessment (*Forms 102, 103*) Dr. Highland & Ms. Sharp**
1. Must have PVDOMICS PI/Co-PI complete
 2. Importance of having all tests/findings available
- Events Reporting**
1. Must have PVDOMICS PI/Co-PI actively participate
 2. Event(s) Notification (*Form 400*)
 3. Event(s) Details (*Form 401*)
 - AE's
 - SAE's (SAEs, Hospitalizations, Deaths)
 - Importance of having all documents/notes available
 4. Submitting supporting documentation (*Form 402*)
 5. Event Review Committee
- 9:20 a.m. Meet the Cores.....Ms. Sherer**
1. Review of Quick Resource Guide – who to contact
- 9:25 a.m. Cardiac Imaging Core Ms. Park**
1. AG Mednet
 - Obtaining Account to transfer images
 - Receipt of images acknowledgement
 2. Echo (*Form 250*)
 3. MRI (*Form 251*)
- 9:35 a.m. Lung Physiology Core/Pulmonary Function Core..... Mr. Ramos**
1. 6 Minute Walk Test (6MWT)
 2. Spirometry, DLCO, Plethysmography (*Form 270*)
 3. Historical PFTs (*Form 271*)
 4. Transferring de-identified tracings and raw data printouts via secure portal
 5. Core's acknowledgement of tracings and raw data received from Center
- 9:50 a.m. Sleep Study Core Dr. Mehra & Ms. Nawabit**
1. Equipment issues
 2. Sleep Study (*Forms 150, 151, 152*)
 3. Alternative Core approved sleep studies (*Form 155*)
 4. Core's acknowledgement of images received from Center

- 10:05 a.m. Lung Imaging Core.....Dr. Lempel**
1. TeraRecon/iNuition Uploader
 - Obtaining account to transfer CT images
 - Receipt of images acknowledgement
 2. Lung CT (*Forms 252, 253*)
 3. V/Q (*Form 254*)
 4. Final Narrative Reports needed for CT and V/Q scans
 5. Core's acknowledgement of images and reports received from Center
- 10:15 a.m. Break**
- 10:30 a.m. Biorepository Core.....Dr. Comhair & Ms. Peterson**
1. Blood Collection 1 (*Forms 300-303*)
 2. Urine Collection (*Forms 320, 321*)
- 11:30 a.m. Cardiac Physiology Core..... Ms. Kirsop**
1. RHC (includes blood collection 2 - *Forms 280, 304-309*)
 2. ECG (*Form 245*)
 3. CPET (*Forms 290, 291*)
 4. Transferring files, images, printouts, tracings via secure portal
 5. Core's acknowledgement of images, printouts received from Center
- 12:00 p.m. Lunch – catered**
- Move to room MM1-106 following lunch**
- 1:00 p.m. Collecting Quality Research Data Ms. Sherer**
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
- 1:10 p.m. How to Enter Forms Ms. Wiggins & Mr. MacKrell**
1. Data entry overview
 2. Assigning participant ID numbers (*Form 100*)
 3. How to identify drugs using WHODrug look-up table (*Form 110*)
- 1:30 p.m. Data Discrepancy Resolution.....Ms. Wiggins & Mr. MacKrell**
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
- 2:00 p.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)
 - Open a previously entered form
 - Change data/make a change data request
 - Respond to an inquiry

2:45 p.m. SSH Data/File Transfer Mr. MacKrell

1. Setting up account for the first time
2. File naming conventions

2:55 p.m. QC Dr. Highland & Ms. Radeva

1. Review of DCC Reports
2. QC Committee (deviations, violations)
 - 80/80 Data Entry Completion Metric
3. Reimbursements

3:30 p.m. Questions and Other Issues Drs. Beck & Ms. Sharp

4:00 p.m. Adjourn