

Chapter 81. Lung Imaging Core - Chest Computed (CT) Tomography

81.0 General Information

The PVDOMICS Study Lung Imaging Core (LIC) is located at the Cleveland Clinic in Cleveland, Ohio. It is under the direction of Jason Lempel, MD, who serves as its director. He oversees LIC personnel and provides standardization, secondary interpretation and data analysis of all chest CT imaging performed for the PVDOMICS Study.

Dr. Lempel provides direction and training on chest CT imaging for the PVDOMICS Study to the local study centers' CT technologists.

Local center chest CT imaging procedures are described in detail in Chapter 80.

Dr. Lempel's contact information is located in the PVDOMICS Address Directory located at http://qhsapps.ccf.org/pvdomics/General_info.htm. Click on 'Address Directory.'

81.1 Training of Local Site Personnel

The Lung Imaging Core will provide training for local sites techs and coordinators as follows:

- o Initial PVDOMICS Study central training
- o Webinar for software installation and use
- o Review and provide feedback to local center on transfer of test case
- o Individual guidance by LIC Radiologist(s)

81.2 Core Image Analysis

Upon receipt of the CT scan at CT Core, a Core radiologist will review the CT data to ensure that the correct protocol for image acquisition and reconstruction was performed. An additional review of the CT images will then be performed looking for motion artifacts and incomplete imaging of the lungs.

Note: Core radiologists will provide feedback regarding image quality if suboptimal/inadequate. At the minimum, a full lung field of view is necessary for core imaging interpretation of PVDOMICS data in order to accurately categorize the type of lung disease.

Following image review for quality assurance, objective measures of vascular and pulmonary morphology will be performed.

81.3 CT Imaging Core Reporting

The DCC will not provide a clinical report on any current or historical CT scan. Specific questions regarding local CT scans obtained as part of PVDOMICS can be directed toward each center's lead PVDOMICS radiologist(s) or the LIC's radiologist(s).

Data collected following review of CT scans are obtained for research purposes only. Therefore, the Chest CT Imaging Core will not provide a detailed reading of the CT scans for abnormal findings that may be of medical concern. Each one of these scans should be reviewed by the Clinical Radiology service at each institution. Examples of these findings include, but are not limited to: incidental lung nodules, incidental breast masses and vascular abnormalities.

All actionable, clinically important findings that are discrepant between the submitted clinical report and the Chest CT Imaging Core over read will be emailed to the local center's PI and study coordinator.

Deviations from PVDOMICS MOP must be reported to the Lung Imaging Core. Follow clinical center guidelines for reporting to IRB.

81.4 Lung Imaging Core QC and Feedback

After data has been reviewed by a LIC radiologist, Form #262 will be completed and entered into the PVDOMICS database at the DCC. In addition to data analysis, review will include image quality and level of adherence to scanning parameters. Significant deviations from prescribed CT scanning parameters which may include, but are not limited to, excessively large or small imaging field of view, abnormal radiation dose and inadequate data transmission will be documented and emailed to the local center's study coordinator and PI.

81.5 Storage of Chest CT Images and Data at Lung Imaging Core

Images, data analysis and reports evaluated at and provided by the Core will be stored on a dedicated iNtuition research server within a secured, password encrypted PVDOMICS folder. These data will also be backed up on a secured encrypted Cleveland Clinic network server during the duration of the PVDOMICS study.

At completion of the PVDOMICS study, data images will be transferred to the NHLBI's Biobank for long term data storage.