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1. INTRODUCTION

This manual describes technical features of dopamine transporter (DAT) single photon emission computed tomography (SPECT) and magnetic resonance imaging (MRI) for the study protocol entitled Parkinson Progression Marker Initiative (PPMI) and includes information about camera quality control and calibration, scan acquisition protocols, image processing and analysis and file transfer to the core imaging lab.

1.1 Background

The underlying goal is to establish biomarker outcomes for PD progression that would accelerate drug development of disease modifying drugs.

a. Develop a comprehensive and uniformly acquired Parkinson disease clinical and imaging dataset with blood and CSF sampling that could be used to identify and validate clinical, imaging and biomic biomarkers of PD progression
b. Establish standardized protocols for acquisition, transfer and analysis of clinical, imaging and biomic data that can be used by the PD research community
c. Investigate existing and identify novel clinical, imaging, and biomic Parkinson disease progression markers to identify individual measures or a combination of measures that demonstrate interval change in PD patients in comparison to healthy controls and/or in PD patient subgroups
d. Conduct preliminary verification studies on promising biological markers using stored collected samples
The development of biomarkers of PD progression can dramatically accelerate clinical research on disease modifying PD therapeutics. Biomarkers may be directed at a specific clinical feature of PD, such as motor dysfunction or dementia or a potential underlying pathophysiology like inflammation or protein misfolding. Given the clear heterogeneity in the onset and progression of PD, several biomarkers with a focus ranging from clinical symptoms to pathophysiological mechanisms will likely be necessary.

Currently within the field of PD biomarker research, most activity focuses on either small-scale biomarker discovery studies or biomarker verification studies, both of which utilize biological samples/clinical information and imaging markers collected through various studies/trials and under differing protocols, which raise questions about the generalizability of results. There is currently no infrastructure in place to allow for systematic and rigorous verification and testing of biomarkers under strict standardized protocols.

PPMI is a multi-centre study designed to determine the individual and joint utility of a selected set of clinical and biological outcome measures. PPMI will integrate prospectively- and systematically-collected clinical data (e.g. phenotypic features, family history, demographic characteristics), imaging data and data from biological specimens. Clinical (including neuropsychiatric, cognitive, quantitative motor), imaging markers, and biological markers (serum, CSF DNA), will be measured. PPMI will also serve to test and establish standardized methods of acquiring biologics and imaging, so that these tools could be assessed reliably in this and future studies.

1.2 Technical Features of PPMI
The development of multi-center quantitative measures, even in the context of a with-in subject design like PPMI, requires a more robust approach to camera calibration, image acquisition, and technical optimization than is necessary for qualitative diagnostic imaging. In this regard, the PPMI study incorporates several unique and investigational technical features to ensure the highest level of data which may be successfully pooled across the study sites and imaging centers. These technical features designed to accomplish this goal in PPMI include:

1) Individual technical site visits and image protocol set-up with optimization of camera protocols and standardization of sites’ processing methods,
2) Dual energy window acquisition of imaging data with incorporation of a $^{57}$Co phantom imaged each day a PD subject is scanned and thus providing a means for the potential correction of the $^{123}$I data based on the phantom,
3) Ongoing core imaging lab assessment of images as they are obtained via rapid quality control check of the imaging data submitted to the core lab and feedback to the imaging site.

**Figure 1**

Energy spectrum for $^{57}$Co and $^{123}$I demonstrating the ability of modern gamma cameras to resolve these energy photopeaks. The study utilizes a dual energy window acquisition which makes the assumption that any changes affecting
the $^{123}$I window would likely similarly affect $^{57}$Co window, hence permitting correction of $^{123}$I with $^{57}$Co phantom.

2. SITE QUALIFICATION PROCESS

To ensure that a site chosen as a participating imaging center meets the high level of standard required by the Imaging Core Lab (ICL), the Institute for Neurodegenerative Disorders (IND), the selected site will complete the following qualifying steps listed below:

2.1 Completion of the SPECT Imaging Site Qualification Questionnaire:

This form (completed by the site) provides IND with contact information for key individuals, specific camera and computer system capabilities, and other specifications necessary for satisfactory completion of the study.

The completed questionnaire is reviewed by IND for initial assessment of the site’s technical capabilities. If the site meets the technical standards required to perform as a participating center, IND will contact the site informing them of the next steps necessary for completion of the qualification process for the study described in the following paragraphs.

2.2 Test Data Acquisition and Data Transfer:

Sites will be required to electronically transfer the test data (via DICOM push, sFTP, FTP or CD) to IND. This test data set can be a previously acquired de-identified (anonymized) subject data set or a point source. Sites will be provided with instructions on the transfer process. For the transfer, an IND staff member will be available to provide technical support to assist the site with the electronic transfer of the point source data. This serves as a test to discover any file transfer problems.

The site will receive a brief communication describing the quality control procedures performed on the test data set. Once the test data set has passed quality control (QC), a member of IND’s Core Lab team will contact the site to schedule the site technical site visit.

2.3 Technical Site Visit and Phantom Acquisition:

During the technical site visit both an $^{123}$I cortical phantom distributed source and an $^{123}$I anthropomorphic striatal phantom will be acquired. Both
acquisitions (projection data) will be transferred to IND for review and reconstruction. The site will receive a communication describing the activities that took place during the technical site visit as well as the QC procedures performed on the phantom acquisitions. This communication will notify the site staff whether or not they are qualified to begin imaging subjects in the study.

2.4 First Subject Acquisition:

After the first subject has been imaged, the site will be instructed to promptly transfer the data to IND for review. The site will be instructed NOT to enroll a second subject until IND has reviewed the first subject data and it has passed both the technical and scientific quality control procedures at the Core Lab.

Once the first subject data has passed both technical and scientific QC, the site will be sent a brief report indicating that they have been cleared to begin enrolling additional subjects.

The above steps are necessary to ensure that imaging sites follow protocol and source documentation guidelines, and image acquisition and data transfer procedures in order to produce data that is deemed acceptable by IND’s quality assurance processes.

3. TECHNICAL SITE VISITS

3.1 Preparation for the site visit

Participating sites will be visited by a core lab representative prior to the initiation of subject enrollment for the purpose of familiarizing nuclear medicine technical staff with image acquisition, processing, data archiving, and data submission procedures. Prior to the technical visit, a $^{57}$Co striatal phantom will be shipped to the site. This phantom will remain at the site for the duration of the study and be used to monitor camera performance and potentially correct for problems with the image data.
57Co striatal phantom used for correction of 123I-DaTSCAN™ subject data. This phantom is provided to each site and acquired each time a PD subject is scanned using the identical dual-energy window acquisition protocol.

Approximately one month prior to the anticipated enrollment of subjects into the study a technical site visit will be scheduled. An agenda will be customized to the requirements of the site and clinical demands on the SPECT camera.

3.2 Technical Site Visit

During the visit, the site set up specialist will review the site’s SPECT instrumentation, collimators, and image processing software in order to develop an image and data processing plan for the site which supports pooling of quantitative DaTSCAN™ data with other imaging sites. In addition procedures for pharmaceutical dose assay, thyroid blockade and safety, fiducial marker placement, image reconstruction and processing, file-naming, and data transfer procedures will be reviewed.

The technical site visit is usually conducted in two sessions over one day. The site set up specialist understands that demands for camera time may influence the timing of the phantom acquisition and every means will be taken to be flexible around the scheduling of the visit activities. A general agenda for a typical site visit is described below:
3.2.1 Technical Site Visit Agenda

Purpose
- Review subject flow and site study roles, responsibilities, and communication
- Review imaging procedures, rationale, and source documents
- Set up dual energy window acquisition protocol
- Perform initial $^{57}$Co phantom acquisition
- Acquire $^{123}$I cortical phantom distributed source
- Perform $^{123}$I anthropomorphic striatal phantom acquisition
- Do test run of data send operation to core lab
- Go over quality assurance program and assessments to occur during the study
- Review mechanisms for feedback from core lab after each image send
- Answer any questions, anticipate problems and solutions
- Confirm contact information
- Provide Site Study Binder containing:
  - Contact information
  - Technical Operations Manual
  - Camera QA Event Log forms (see Figure 4 for an example)
  - Instructions for completion of Camera QA Log
  - SPECT Scan Information Source Documents with instructions for completion (see Figure 5 for an example)
  - sFTP/FTP server, user, and password information or DICOM server information exchange
  - SPECT Imaging Data Transfer Information Source Documents (see Error! Reference source not found. for an example)
  - Site specific subject numbering protocol
  - Core Lab communications section for maintaining records of all communication with the Core Lab

Agenda

Session 1 about 1 h

Suggested participants: Neurology PI, Nuclear Medicine PI, study coordinator, nuclear medicine technologist and other key members of the neurology and nuclear medicine teams

1) Introductions and orientation

2) Outline of study technical imaging features
3) Review individual team members’ responsibilities and communication from recruitment, to consenting and enrollment, to scan scheduling, image acquisition, etc.

4) Review core imaging lab technical documents and data submission procedures

5) Review imaging core lab quality control procedures

**Session 2 (about 4 h)**

Participants: nuclear medicine group

1) Briefly tour the imaging facilities and review study camera(s)/collimators and quality assurance procedures, document system software and version

2) Develop a dual-energy window acquisition protocol ($^{57}$Co and $^{123}$I windows) for specific SPECT tomograph to be used in the study

3) Test the acquisition protocol with three phantom acquisitions, one a $^{57}$Co phantom, the other two anthropomorphic $^{123}$I phantoms The imaging core lab representative provides and prepares all the phantoms working with the site’s technologist staff. The site must have 37-111 MBq (1.0-3.0 mCi) of liquid $^{123}$I available for the phantom acquisition. Phantom acquisitions will be scheduled according to camera availability.

4) Review imaging data transfers procedures to the imaging core lab. Perform a dry run of acquired phantom data transfer, troubleshoot problems, firewall issues, etc.

5) Provide information about on-going follow-up and communication, final questions, and wrap-up.

Following the technical site visit, a report summarizing the technical acquisition and reconstruction parameters, image analysis, and file transfer procedures will be sent to the site. This will also document the quality assurance program discussed for the camera. This technical report should be kept in the study binder and serve as a proscriptive technical summary for the site. Any modification or changes in image acquisition will be reflected in updates to the technical site visit report and may also be stored in the site study binder.
4. NUCLEAR MEDICINE PROCEDURES

4.1 Quality control and camera calibration

Instrument assessment and quality control measures are critical to the meaningful interpretation and pooling of quantitative SPECT data across study sites. These measures and calibrations may be considered to occur over two periods; 1) prior to subject enrollment and, 2) after the initiation of patient enrollment.

Within the month prior to the initiation of each site must have completed the following planar and SPECT Q/C data: $^{99m}$Tc flood uniformity corrections with the clinical imaging collimators in place, COR correction, and energy correction according the manufacturers’ specifications for the instrument. During the technical site visit the imaging core lab representative will verify the clinic’s quality assurance procedures and an additional three phantoms will be obtained as outlined above: 1) a $^{57}$Co striatal phantom, 2) an $^{123}$I cortical distributed source phantom, and 3) an $^{123}$I anthropomorphic striatal phantom.

After initiation of the study, quality control procedures will include the following: $^{57}$Co striatal phantom acquired each day a subject is imaged using the dual energy window protocol established during the site visit. This phantom permits on-going assessment of the camera over the course of the trial and allows for a correction of the $^{123}$I-DaTSCAN™ data. Other quality control measures will be performed according to the clinic’s and camera
manufacturer’s standard procedures as implemented in the site’s quality control program for the SPECT camera and dose calibrator.

The minimal required calibration and quality control studies are summarized in Table 1 and need to be documented on the Camera QA log when performed:

<table>
<thead>
<tr>
<th>Test</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performed prior to subject enrollment by IND team</strong></td>
<td></td>
</tr>
<tr>
<td>$[^{123}]$I distributed source phantom</td>
<td>Provides an empirical measure of linear attenuation coefficient $\mu$ (cm$^{-1}$) for homogeneous attenuation correction, sensitivity</td>
</tr>
<tr>
<td>$[^{123}]$I Striatal phantom</td>
<td>Allows baseline measure for evaluation and comparability of recons, region sampling, etc</td>
</tr>
<tr>
<td>$^{57}$Co striatal phantom</td>
<td>Determines a correction factor for cross-camera calibration of specific:nonspecific uptake ratio</td>
</tr>
<tr>
<td><strong>Performed during study each day a protocol subject is scanned</strong></td>
<td></td>
</tr>
<tr>
<td>$^{57}$Co striatal phantom</td>
<td>Provides ongoing assessment of camera sensitivity, means for correcting PD data</td>
</tr>
<tr>
<td>Routine SPECT and dose calibrator QC</td>
<td>Maintains integrity of camera and dose calibrator</td>
</tr>
</tbody>
</table>

The Camera QA Event log will be completed on days when subject images are acquired. In addition, quality assurance data, software upgrades, changes in hardware and any other manipulations or changes to the imaging camera are to be recorded in a Camera QA Log source document which will be provided to the sites during the technical site visit. See Figure 4 next page.
Figure 4

Camera QA Event Log. This log records any QC, software changes, etc. to the camera and acquisition computer as well as scan day QC floods. All logs up to and including the date of each subject scan should be faxed with other source documents at the time of the transfer of the image data.

All current “Camera QA Event Logs” should be faxed along with the subject “Scan Information Source Document” (Figure 5) and “Imaging Data Transfer Information Source Document” (Figure 7) following a subject scan.

4.2 Image acquisition

Subjects with Parkinson disease will have DaTSCAN™ imaging at screening and at months 12, 24, 36, 48 and 60. Healthy control subjects will have DaTSCAN™ imaging at screening. Radiopharmaceutical will be provided as a unit dose. Specific details of ordering the DaTSCAN™ dose will be discussed at the site visit. The dose should be assayed in a 10 ml syringe filled to a standard volume of 6 ml. In order to avoid geometry effects on determination of actual injected dose following injection of DaTSCAN™, the syringe should be reassayed. These data should be recorded on the PPMI Scan Information Source Document (Fig 5). Subjects should be pretreated...
with saturated iodine solution (10 drops in water) or perchlorate (1000 mg,) prior to DaTSCAN™ injection. The target dose for subjects will be 185 MBq or 5.0 mCi of DaTSCAN™. The dose range for injection is 111 to 185 MBq. Do not exceed 185 MBq and do not use when the activity is below 110 MBq. Subjects are to be imaged 4 ± 0.5 hours later. Specifically-bound activity washes out from striatal binding sites slowly, but not negligibly, hence every effort should be made to maintain a consistent imaging time post injection of DaTSCAN™.

![Scan Information Source Document](image)

### Figure 5

Scan information source documents the radiopharmaceutical dose, time imaging post-injection, the phantom and subject acquisition parameters. This form is completed for each subject and sent to core lab at the same time the images are transferred.

Immediately prior to imaging, subjects should have the supplied $^{57}$Co line markers affixed along the canthomeatal line as demonstrated during the
technical site visit (Fig. 6). Two sets of $^{57}$Co markers are provided to the sites. Each set contains one line with two point markers embedded at the ends of the tube and one line with $^{57}$Co point markers at the ends and in the middle of the tubing. The line marker with two point sources attached to the right, while the line marker with three point sources attaches to the left. This facilitates subsequent image processing and allows the core lab to accurately distinguish left and right in the face of multiple image file transfers. The markers will only be evident in the $^{57}$Co window and hence will not contaminate the $^{123}$I-DaTSCAN™ brain data.

Figure 6

Demonstration of $^{57}$Co line markers affixed along the canthomeatal line (left). The markers may be affixed with paper tape or other means with the two-point marker line on the right and the three marker line on the left.

As a general protocol, raw projection data will be acquired into a 128 x 128 matrix stepping each 3 degrees for a total of 120 (or 4 degrees for a total of 90) projections into two 20% symmetric photopeak windows centered on 159 KeV and 122 KeV with a total a scan duration of approximately 30 – 45 minutes. Specific scan parameters including collimation and acquisition mode will be selected for each site on the basis of an assessment during the technical site visit. Insofar as possible, it is recommended that acquisition be in step and shoot mode with each head rotating 360 degrees using a parallel hole collimator to permit the reconstruction of a viable image even if one head is faulty. The acquisition parameters for each study are recorded in the scan information sheet source document at the time of the scan as indicated in Fig. 5.
4.3 Data Interpretation

A visual interpretation on all screening visit DaTSCAN data will be performed at the imaging core lab by well-experienced nuclear physicians. Sites will receive a report indicating whether there is evidence of a dopamine deficit on the subject’s scan. The imaging interpretation will serve as final criteria for enrollment into the study.

5. IMAGE RECONSTRUCTION, PROCESSING, SCAN IDENTIFICATION AND ARCHIVING

5.1 Imaging Reconstruction and Processing

Both the imaging site and the core lab will reconstruct and attenuation correct the imaging data comprised of both the subject’s data and the cobalt striatal phantom acquired each day a subject is scanned. Imaging sites may implement either filtered back-projection or an iterative reconstruction algorithm using standardized approaches. Methods for homogeneous attenuation correction (Chang 0) and regional striatal analysis for extraction of count densities and determination of specific uptake ratios will be reviewed during the technical site visit.

5.2 Scan Identification

Each set of data transferred to the imaging core lab will be identified in the following manner:

For C057 phantom data:

-3 digit site code followed by date of acquisition (DDMONYR) format

Example for phantom data acquired from site 023 on February 19, 2010 will be indentified as “02319FEB10”

For subject data:

-3 digit site code followed by 4 digit subject number followed by _ and the scan visit number:

1 = Scan 1 (screening visit)
2 = Scan 2 (Month 12/Visit 4)
3 = Scan 3 (Month 24/Visit 6)
4 = Scan 4 (Month 36/Visit 8)
5 = Scan 5 (Month 48/Visit 10)
6 = Scan 6 (Month 60/Visit 12/Premature Withdrawal;
Example for the Month 36/Visit 8 scan for subject number 1455 acquired from site 023 will be indentified as “0231455_4”

5.3 Study Data Archiving

ALL SPECT raw and reconstructed study data should be archived prior to transfer to the Core Lab. These represent source data. The method of archiving should follow site specific Standard Operating Procedures (SOPs). Additionally, all study related source documentation should be maintained in the appropriate section of the Study Binder. All queries and/or correspondence will also need to be maintained and filed in the Study Binder. All study documentation and SPECT data must be retained by the site in accordance with the protocol.
6. DATA TRANSFER

Individual site issues regarding transfer of image data will be addressed at the technical site visit. Each site will be provided with transfer instructions. If necessary, the imaging core lab representative will assist the site in the implementation of transfer procedures. **It is recommended that image files be in DICOM3 format, although native scan format is also acceptable.** For each scan, and depending upon the camera manufacturer, the following files should be submitted to the core lab:

1) DaTSCAN subject: raw projection data for both $^{123}$I and $^{57}$Co windows
2) DaTSCAN subject: reconstructed image files for both $^{123}$I and $^{57}$Co windows
3) $^{57}$Co phantom done on the subject scan day: raw projection data for both $^{123}$I and $^{57}$Co windows
4) $^{57}$Co phantom done on the subject scan day: reconstructed image files for both $^{123}$I and $^{57}$Co windows

Using the procedures detailed in the previous section, the site should record the data to be sent on the scan information and data transfer source documents (Fig. 5 and 7.). These source documents should be sent to the imaging core lab. Receipt of the source documents at the imaging core lab serves to notify the imaging core lab team that data have been electronically transferred. The imaging core lab will then review the imaging data against what was received to check for the presence of all expected data. All data will be interrogated for accuracy and completeness using a standard quality assurance procedure. If there is a problem with the data file sent, an imaging core lab representative will contact the site staff. Depending upon the nature of the problem, the resolution may involve simple provision of additional information, the resend of one or more image data files, or other action to ensure the completeness of the image data files.
7. MAGNETIC RESONANCE IMAGING

In the present study, a non-contrast enhanced, T2 weighted brain MRI using at least a 1.5 Tesla scanner and a non-contrast enhanced 3D volumetric T1-weighted brain MRI will be performed at baseline for all subjects. Therefore, it is required that the radiology site (or person identified as responsible) transmit the MRIs to the imaging core lab. All MRI sequences should be transmitted to the imaging core lab.

7.1 MRI Acquisition Procedures

A T1-weighted, 3D sequence (e.g. MPRAGE or SPGR) is required. The total scan time is expected to be in the range from between 20 – 30 min. The field of view (FOV) must include the cerebellum and pons. A typical sequence for the T1 sequence is described below:
### Type of sequence

<table>
<thead>
<tr>
<th>TR (ms)</th>
<th>5 – 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE (ms)</td>
<td>2 – 6</td>
</tr>
<tr>
<td>Slice thickness (mm)</td>
<td>1 – 1.5</td>
</tr>
<tr>
<td>Interslice gap (mm)</td>
<td>0</td>
</tr>
<tr>
<td>Voxel size (mm)</td>
<td>1<em>1</em>1.2</td>
</tr>
<tr>
<td>Matrix</td>
<td>256 x minimum 160</td>
</tr>
<tr>
<td>Plane</td>
<td>Sagittal</td>
</tr>
</tbody>
</table>

For detailed assessment of cerebral vasculature, a T2-weighted double-echo and FLAIR sequence should also be performed. This scan can be acquired according to the imaging protocol used routinely at the respective investigative site and need to be sent to the imaging core lab.

### 7.2 MRI Transmittal Procedure to IND

The T1-weighted, 3D volumetric MRI and all other sequences must be forwarded to the imaging core lab in DICOM 3.0 format. These can be sent either by sFTP transfer, direct DICOM transfer, or on CD and each MRI should be labeled according to the file naming procedure specified below in Section 7.3.

An MRI Transmittal Form will be sent to the imaging core lab with each MRI transmission.

**Please note:** MRI images should be sent de-identified (i.e. no patient names or dates of birth). Also, if CDs are sent, please make sure that both the CD case and the CD itself are labeled with Site ID#, Site Name and subject PID#.

### 7.3 MRI ID

Each set of MRI data transferred to the imaging core lab will be identified in the following manner:

- 3 digit site code followed by 4 digit subject number followed by _ and the scan visit number:
  - 1 = MRI 1 (Baseline)

Example for the Baseline MRI for subject number 1455 acquired from site 023 will be identified as "0231455_1"
8. STUDY TECHNICAL DOCUMENTATION

The key to technical documentation is the technical binder. It is recommended that the Nuclear Medicine group maintain the technical binder as a single source of information about the imaging aspects of the study, including recording when phantoms are acquired, QC changes, software upgrades, individual scan information sheets, etc. In addition, the technical binder serves as a reference document for the site summarizing all technical procedures for the study. The technical binder contains the following:

- Contact information
- Technical Operations Manual
- Camera QA Event Log forms
- Instructions for completion of Camera QA Log
- SPECT Scan Information Source Documents with instructions for completion
- sFTP server, user, and password information
- SPECT Imaging Data Transfer Information Source Documents
- Site specific subject numbering protocol
- Core Lab communications section for maintaining records of all communication with the Core Lab

The binder will be provided to each site at the technical site set-up visit along with instructions for maintenance of the technical source documents.

9. COMMUNICATION WITH IND AND TROUBLE-SHOOTING PROBLEMS

The description of the imaging data flow underscores the complexity of the trial and highlights the need for timely and efficient communication. All imaging data will be reviewed and the Data Receipt Form will be faxed back to sites. Any queries with the data will be directed to the Nuclear Medicine group at the site based on discussion and contact trees created at the technical site visit. ANY question regarding the technical conductance of the trial, from issues around the receipt of radiopharmaceutical, to camera set-up, subject and phantom scan acquisition, image processing, file creation and transfer, etc are appropriate to direct to IND.

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