

PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research

PPMI

AV -133 PET Imaging Technical Operations Manual

The PARKINSON PROGRESSION MARKER INITIATIVE

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1. Introduction

This manual describes technical features of PET imaging for 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.

2. Imaging Center Qualification Process

To ensure that an imaging center chosen to participate in a study meets the high standards required by the Imaging Core Lab, The Institute for Neurodegenerative disorders (IND) and the study sponsor, Michael J. Fox Foundation for Parkinson's Research (MJFF), the selected imaging center will be required to complete the steps listed below.

2.1 Completion of the PET Imaging Center Technical

Assessment Questionnaire:

This form (completed by the imaging center) 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 center's technical capabilities. If the center meets the technical standards required to perform as a participating center, IND will contact the center informing them of the next steps necessary for completion of the qualification process for the study described in the following paragraphs.

The Radiopharmaceutical License and Shipping form is collected by IND and provided to the radiopharmaceutical manufacturer, Avid Radiopharmaceuticals, so that Avid can set-up proper logistics and ensure that the imaging centers have the proper licenses to accept [¹⁸F]AV-133.

2.2 Test Data Transfer and Data sFTP or Direct DICOM

Transfer:

Imaging centers will be asked to provide a de-identified (anonymized) brain scan (or other test transfer such as a point source) as test data and to electronically transfer the data via direct DICOM push (DICOM node to DICOM node), or sFTP (or via CD if sFTP is not feasible) to IND. All images regardless of transfer method should be DICOM 3.0 compliant. Imaging centers will be provided with instructions for the test data acquisition via e-mail once their Technical Site Questionnaire has completed review.

The preferred method of transfer for the data is via direct DICOM transfer. In order to be able to send IND data via this method, the image center will need to provide the following to IND (please fax this information to 203-401-4303 or send via e-mail to corelab@indd.org) prior to trying to send the data:

- IP Address
- AE Title
- Port #

Once staff at IND receives this DICOM information from the image center, a folder will be set-up on our DICOM server to accept data from the image center. IND's DICOM server information can be found in the Test Data Transfer Instructions (see Appendix 1). In addition to transferring the data, imaging centers will need to complete the PET Test Data Transfer Information Document (Appendix 1) and either fax it to 203-401-4303 or send it via e-mail to corelab@indd.org. Alternatively, imaging centers can send the data via sFTP to ftp.mnimaging.com (a unique site and study-related username and password will be provided when the Test Data Transfer Instructions are e-mailed to the imaging center with the request to acquire and transmit test data). Just as with direct DICOM transfer, in addition to transferring the data, imaging centers will need to complete the PET Test Data Transfer Information Document and either fax it to 203-401-4303 or send it via e-mail to corelab@indd.org.

If an imaging center is not able to send the test data via direct DICOM transfer or via sFTP, then in these rare cases, IND will accept data via CD or DVD. The CD or DVD must be labeled with the study protocol, image center number, acquisition date, and the words "TEST DATA." Along with the CD or DVD, imaging centers must complete the PET

Test Data Transfer Information Document, and send it along with the CD or DVD to:

The Institute for Neurodegenerative Disorders
c/o: Core Lab
60 Temple St.
Suite 8A
New Haven, CT 06510

For the transfer, an IND staff member will be available to provide technical support to assist the imaging center with the electronic transfer of the test data (please refer to Section 9). This serves as a test to discover any file transfer problems.

Please note: Test data needs to be sent using the same exact pathway anticipated to send subject data.

The imaging center will receive an email notification confirming the test data and corresponding document has been received. Once the test data has passed quality control (QC), a member of IND's team will contact the center to schedule the image center Technical Set-up Visit. (See Section 3.0 of this manual for detailed information about the Technical Set-up Visit).

In cases where IND has already received data from an imaging center previously, and the transfer pathway is well established, the requirement to send a test data transfer may be waived.

2.3 Technical Set Up Visit and Phantom Acquisition:

During the technical set up visit (described in Section 3.0) an Anthropomorphic Cortical Phantom (Hoffman 3-D Brain) acquisition will take place and the data sent via DICOM, sFTP or via CD/DVD to IND for review. The imaging center will receive a communication describing the activities that took place during the technical visit as well as notification that phantom acquisitions and corresponding documents were received. If there are any issues with the phantom data, the imaging center will be contacted. After the phantom data has been reviewed and passed the IND QC process, the imaging center and clinical site will receive an Approval to Scan Letter. This communication will notify the imaging center staff when they are qualified to image their first subject.

2.4 First Subject Acquisition:

After the first subject has been imaged, the image center will be instructed to promptly transfer the data (via DICOM push, sFTP, or CD) to IND for review. The image center should NOT 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 center will be sent a brief report indicating that they have been cleared to begin scanning additional subjects.

The above steps are necessary to assure that imaging centers will strictly 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.

3.0 Technical Set Up Visits

3.1 Preparation for the Technical Set Up Visit

Participating imaging centers will be visited by technical personnel from IND consisting of a nuclear medicine physician, physicist, or nuclear medicine technologist prior to the initiation of subject enrollment for the purpose of familiarizing nuclear medicine technical staff with protocol-specific image acquisition, processing, data archiving, and data submission procedures.

Usually one month prior to the anticipated enrollment of the first subject into the study, a technical site visit will be scheduled. A schedule will be customized to the requirements of the image center and clinical demands on the PET camera.

In some cases, where an imaging center has been working with IND on a previous or concurrent trial, a physical site set-up will not be necessary, and IND will schedule a Technical Site Set-Up Teleconference with the imaging center in lieu of the physical visit.

3.2 Technical Set Up Visit

A representative from IND will review the image center's PET instrumentation and image processing software in order to optimize the image acquisition and data processing plan for the imaging center. The acquisition protocol will be established for the imaging center's PET camera. In addition, procedures for image reconstruction and processing, file-naming, and data transfer procedures will be described.

The imaging center visits are usually conducted in two sessions over one day, or alternatively broken up into an afternoon and morning session over two days depending on the image center's preference and availability of personnel. IND 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. The clinical staff working on the project are invited and encouraged to attend the presentation portion of the visit.

A general agenda for a typical site visit is described below:

3.2.1 *Technical Site Visit Purpose*

- Review subject flow and image center study roles, responsibilities, and communication
- Review imaging procedures, rationale, and documents
- Review of [^{18}F]AV-133 ordering procedures
- Develop camera-specific acquisition protocol
- Perform ^{18}F acquisition emission and transmission scan of a Hoffman 3-D Brain Phantom
- Review reconstruction and attenuation correction procedures
- Review image center's data transfer capabilities and transmit phantom acquisition data to IND for review (data may also be burned to CD if sFTP or direct DICOM transfer is not possible).
- Go over quality assurance program and assessments to occur during the study
- Review mechanisms for feedback from the Core Lab after each image is received
- Answer any questions, anticipate problems and solutions
- Confirm contact information
- Discuss Adverse Event Reporting Procedures, provide Image center Study Binder (see Section 8 for contents)

3.2.2 Agenda

Session 1 (about 1 hour)

A general agenda for a typical center visit is described below:

Suggested participants: Study Site Principal Investigator, Nuclear Medicine physician (if different from study Principal Investigator), study coordinator, nuclear medicine technologist and other key members of the neurology and Nuclear Medicine teams.

- 1) Introductions and orientation (15 min).
- 2) Brief background on [18F]AV-133 imaging (15 min).
- 3) Outline of study technical imaging features (15 min).
- 4) Review individual team members' responsibilities and communication from recruitment, to consenting and enrollment, to scan scheduling, image acquisition, etc.

Session 2 (about 3-4 hours)

Suggested participants: Nuclear Medicine group

- 1) Briefly tour the imaging facilities and review study camera(s) and quality assurance procedures, document system software and version (15 min).
- 2) Test the acquisition protocol with a Hoffman 3-D Brain Phantom (Figure 1) acquisition– this can be done after hours given the busy clinic schedule. The representative from IND provides and prepares all the phantoms working with the image center's technologist staff. We would ask for 1.0 mCi of ^{18}F be available (time required depends on clinic).
- 3) Review imaging data transfer procedures to the Core Lab in New Haven, send acquired phantom data, troubleshoot problems, firewall issues, etc (if necessary). (30 min)
- 4) Provide information about on-going follow-up and communications, final questions, and wrap-up (20 min).

Following the technical visit, a detailed report summarizing the technical acquisition and reconstruction parameters, image analysis, and file transfer procedures will be sent to the image center. 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 prescriptive technical summary for the image center. Any modification or changes in image acquisition will be reflected in updates to the technical visit report and must also be stored in the imaging center study binder.

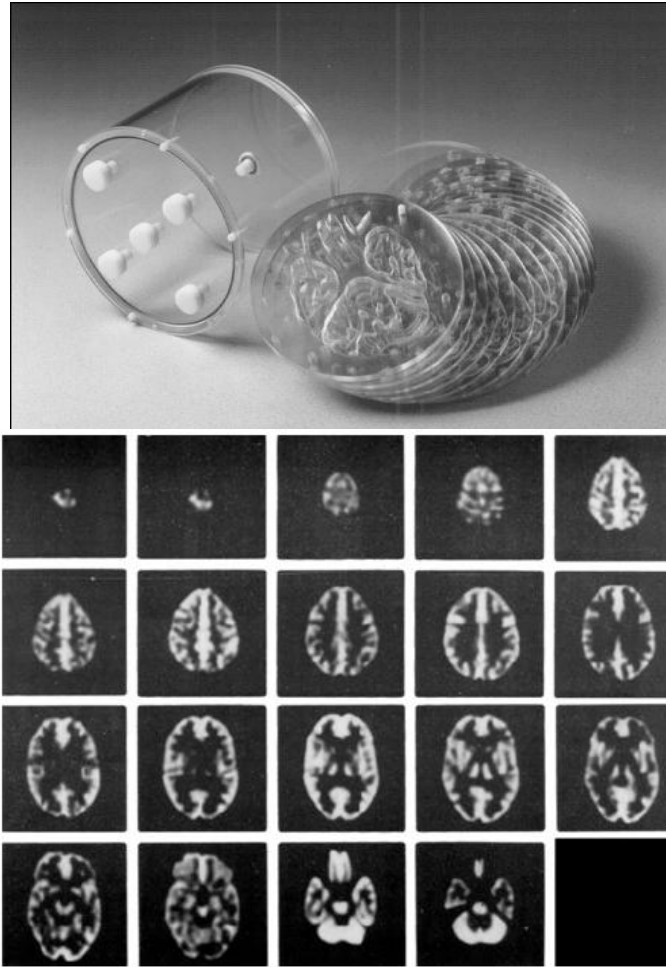


Figure 1: Hoffman 3-D Brain phantom for initial center calibration during technical center visit. This will be filled with ^{18}F and the data used to optimize and standardize the reconstruction and filtration of the PET image across the different imaging centers.

4.0 Nuclear Medicine Procedures

4.1 Quality Control and Camera Calibration

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

During the technical site visit, the clinic's quality assurance procedures will be reviewed and an ^{18}F anthropomorphic cortical phantom acquired.

Quality control measures will be performed according to the clinic and camera manufacturer standard procedures as implemented in the image center's quality control program for the PET camera and dose calibrator.

For dedicated PET cameras: The scanner should have an up-to-date calibration and normalization on the date of each imaging session. In addition a daily QC/blank scan (empty port transmission) should be done at the beginning of the day on which the scanning is to be completed. The QC sinogram should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the study should be rescheduled.

For PET/CT systems: The scanner should have an up-to-date calibration and normalization on the date of the imaging session. A daily QC check should be done at the beginning of the day on which the scanning is to be completed. This scan should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the study should be rescheduled. Daily CT QC should be performed as recommended by the camera vendor, but typically should include a "checkup/calibration" procedure and a water phantom scan. The checkup/calibration procedure guarantees optimum image quality by warming up the x-ray tube and should be performed at startup and within 1 hour prior to any scan. The water phantom provides quality measurements of 3 parameters, including the CT value of water calculated in Hounsfield units (HU), the pixel noise of images calculated as a standard deviation, and the tube voltages measured directly on the x-ray tubes. These three measurements should be determined for all intended kVp values.

Quality assurance data, software upgrades, changes in hardware and any other manipulations or changes to the imaging camera will be recorded in a Camera QA Event Log source document which will be provided to the imaging centers during the technical site visit (Appendix 2).

This monthly log records any QC, software changes, etc to the camera and acquisition computer. All (not previously sent) "Event Logs" up to and including the date of each subject scan should be faxed with other

source documents at the time of the sFTP or DICOM transfer of the image data (for data being sent on CD/DVD – please send a copy of the documents in the package with the CD/DVD). The documents that should be sent to IND following a subject scan include:

- Camera QA Event Logs (Appendix 2)
- PET Scan Acquisition Document (Appendix 3)
- PET Imaging Data Transfer Document (Appendix 4)

Quality control of the dose calibrator should be performed throughout the course of the study. This typically will include daily constancy, quarterly linearity and annual accuracy tests. These will be documented and the documents made available for IND inspection.

4.2 18F-AV-133 Information

4.2.1 Investigator's Brochure for 18F-AV-133

18F-AV-133 is an investigational imaging agent and has not yet been approved by FDA. To provide centers with safety information about the compound, a copy of Avid Radiopharmaceutical, Inc.'s Investigator's Brochure for 18F-AV-133 is being provided in the Technical Binder. The Imaging Center personnel (especially the nuclear medicine physician) should review this document.

4.2.2 Radiopharmaceutical Shipping Information and NRC Licenses

Please note that 18F-AV-133 is an investigational imaging agent, and it may be necessary for Imaging Centers to amend their radiation license in order to be able to receive this compound. IND will be sending the imaging centers a "Radiation License and Radiopharmaceutical Shipping Information Document" (Appendix 5) to be completed as well as a request for the image center's license. Once IND receives these completed forms and the license, they will be sent to Avid Radiopharmaceuticals for their review to determine if they can legally provide 18F-AV-133 to the imaging center under their current license. If it is determined that the image center may need an amendment to their license, IND will notify the image center. IND and Avid Radiopharmaceuticals are available to the imaging centers to assist with license amendment issues.

4.2.3 18F-AV-133 Dose Ordering Procedure

Avid Radiopharmaceuticals, Inc. has provided detailed guidance for the ordering of doses of the radiopharmaceutical being used in this trial. Instructions and examples of relevant forms are provided in the "Avid Clinical Supplies Guidance Document" found in your technical binder. All questions regarding 18F-AV-133 dose ordering should be directed to:

Avid Contacts	
Carly Kline	
Email	kline@avidrp.com
Phone Number	+1 - 215-298-9537
Fax Number	+1 - 215-689-4804
Jennifer Payne	
Email	payne@avidrp.com
Phone Numbers	(work) 215-298-0731 (cell) 215-410-7471
Fax Number	215-689-4804

It is important to note that AV-133 must be ordered at least 48 hours in advance of when the dose is required at the imaging center. The Imaging Center and the Clinical Center will decide whose responsibility it will be to complete the "Avid Drug Request Form". This document should be completed as soon as a subject is scheduled for a 18F-AV-133 PET scan and faxed to Avid Radiopharmaceuticals to the fax number on the form. Avid will then coordinate with the manufacturing center and the imaging center to provide an expected arrival date and time for the radiopharmaceutical at the imaging center.

Note: It is recommended that imaging centers schedule subjects for 18F-AV-133 imaging later in the day and attempt to schedule more than 1 subject at a time if possible.

It is the responsibility of the imaging center to ensure that they have the necessary equipment for dosing subjects and to inform IND prior to the Technical Site Set-Up visit if they do not.

4.2.4 Investigational Product Control

The receipt of ¹⁸F-AV-133 must be documented at the site.

All drug supplies for this trial should be retained in a safe and secure place at all times during the trial. ^{18}F -AV-133 for injection should be administered by qualified personnel at the Imaging Center. An up-to-date drug inventory/dispensing record must be maintained. The empty unit dose syringe should be disposed of according to institutional practices.

4.2.5 Timing of the ^{18}F -AV-133 PET Scans

^{18}F -AV-133 PET imaging can be performed up to four times for each subject:

For PD Subjects:

- Screening
- Month 12/Visit 4
- Month 24/Visit 6
- Month 48/Visit 10
- Premature Withdrawal (if scan not acquired within the last 12 months)

For Healthy Controls:

- Screening

For SWEDD Subjects:

- Screening
- Month 24/Visit 6

Please make sure you receive the correct visit and scan interval from the study coordinator.

For sites located in the United States ^{18}F -AV-133 PET scans will occur at the visits indicated above, approximately 1-3 weeks after completion of the SPECT DAT imaging.

4.3 Image Acquisition

4.3.1 PET Set-Up

The subject will undergo a total of 20 minutes of PET imaging over two 10 minute imaging sessions starting 50 minutes \pm 5 minutes and 80 minutes \pm 5 following injection of ^{18}F -AV-133 and undergo safety assessments. It is crucial to pay particular attention to ensuring the

subject is comfortable on the imaging bed. The PET camera should be set up for 2 imaging sessions:

- 2 serial 5 min acquisitions, starting at 50 ± 5 min post 18F-AV-133 injection and
- 2 serial 5 minute acquisitions, starting at 80 ± 5 min post 18F-AV-133 injection.

Measured attenuation using a transmission source or CT (for PET CT units) is to precede each imaging session. Be mindful of the requirements outlined in the protocol for safety and adverse event assessments.

Please Note: It is imperative there is verification that the dose of 18F-AV-133 has passed QC (via document faxed or e-mailed to the imaging center) prior to injection of AV-133. In some cases, the dose may arrive on-site prior to the QC document. In those cases, the dose should not be administered until the QC document has been received.

Although rare in occurrence, if a dose fails (i.e. does not meet Avid QC) or the dose does not arrive on site, the subject will need to be rescheduled.

4.3.2 PET Acquisition

1. There is no requirement for subjects to fast prior to 18F-AV-133 injection.
2. Women of child bearing potential must have a negative urine pregnancy test performed on the day of injection (prior to injection).
3. Obtain the subject's weight, and document these results on the "**PET Acquisition Document**" (Appendix 3).
4. Vital signs will be obtained in the supine position before the administration of 18F-AV-133 ($5 \text{ min} \pm 1 \text{ min}$ prior to injection).
5. Obtain intravenous access.

6. Draw approximately 6 mCi (222 MBq) of 18F-AV-133 ($\pm 10\%$) and assay with a dose calibrator. Record assay results and assay time on the "**PET Acquisition Document**."
7. Inject the 6 mCi $\pm 10\%$ of 18F-AV-133 as a single bolus within 6 seconds. Followed by an infusion line flush with 15-20 ml of saline.
8. For accurate determination of the dose of injected 18F-AV-133, the empty syringe should be refilled to the same volume as the injection and reassayed in the dose calibrator, recording activity and time of sampling on the "**PET Acquisition Document**" (Appendix 3).
9. Vital signs will be obtained in the supine position 15 minutes (± 5 minutes) post administration of 18F-AV-133.
10. Have subject relax post injection for a 50 minute (± 5 minutes) uptake period prior to the imaging session. No special sensory or room lighting conditions are necessary for this tracer, in contrast to an 18F FDG brain PET.
11. After approximately 40 minutes have elapsed, have the subject empty their bladder prior to the imaging session.
12. Post void, position and secure the subject in the scanner.
13. Acquire low-dose CT or isotope transmission scan, then 2 X 5 minute images per the acquisition/reconstruction parameters detailed below at 50 min (± 5 minutes) after injection.
14. Acquire low-dose CT or isotope transmission scan, then 2 X 5 minute images per the acquisition/reconstruction parameters detailed below at 80 min (± 5 minutes) after injection. It may be more comfortable for the subject to remain on the imaging table for the 20 minutes between imaging sessions.
15. Subjects who experience an AE will not be discharged until the event has resolved or stabilized. **If a subject

experiences an adverse event, the study coordinator must be contacted immediately.

16. A physician or physician's designee will need to see the subject prior to discharge.

4.3.3 Attenuation Correction:

PET only scanners

- Acquire an attenuation correction scan using rod sources for 5 minutes to 10 minutes, all depending on the strength of the rod sources during time of study. This should be done prior to each acquisition.
- Apply segmentation and re-projection routines for attenuation correction.

PET/CT Scanners

- Use standard low dose CT acquisition parameters for attenuation correction. This should be done prior to each acquisition.

5.0 Image Reconstruction, Processing and File Naming procedures

5.1 Image Reconstruction and Processing

Iterative reconstruction of the emission data with correction for scattered photons, randoms, decay and attenuation represents the default reconstruction image set.

***NOTE:** Please ensure that the images are reconstructed using quantitative units such as SUV, Bq/ml, kBq/cc, etc. prior to sending the images to IND. If this is not available on your system, please contact IND prior to sending any subject data to be provided with further instructions.*

Example of an initial PET Emission Acquisition & Reconstruction-This will be evaluated during site set-up and adjusted for system optimization. The Imaging Center Set Up

Report will outline the specific acquisition and reconstruction protocol for your center.

Scanning direction:	Head to foot
# Of Beds:	1 (brain)
Time per Scan:	2 x 5 Minute scans*
Randoms Correction:	On (Prompts – Delays)
Scatter correction:	On (Monte Carlo Simulation based upon CT data model)
Decay Correction:	On
Attenuation Correction:	CT or isotope transmission
Reconstruction Algorithm:	Iterative (OSEM, e.g.4 iterations, 16 subsets)
Image Matrix Size:	128 x128
Zoom:	2
SFOV:	600 mm
Slice Thickness:	4 mm (match slices to CT slices)
Post reconstruction Filter:	Gaussian FWHM 5.0 mm

***Please note that the technical set-up visit will determine the final imaging protocol to be used for centers that cannot acquire dynamic scans.**

The following is an example of a CT Scan (Transmission Scan Acquisition and Reconstruction Protocol)

A low-dose CT acquisition of the head is acquired using the following suggested parameters (although this will be evaluated during site set-up and adjusted for system optimization):

Tube voltage:	120 kVp
Care Dose 4D Reference Current:	55 mA
Acquisition type:	Spiral
Pitch:	0.8
Collimation:	1.2 mm
Slice Thickness:	5 mm
Slice Interval:	3 mm
Rotation:	0.5 sec
SFOV for transmission scan:	700 mm
SFOV for registered image:	500 mm
Image matrix:	512 x 512

Make sure to:

- 1) Review images to assess for artifacts and subject motion.
- 2) Review images for excessive noise, low counts and subject positioning.
- 3) Imaging centers must ensure they archive the reconstructed imaging data for this study as these represent the source data and must be kept at the imaging center. Additionally and if possible, raw (sinogram) data should be archived as well.
- 4) QC headers for subject identification, HIPAA conformance and correct dynamic time point information.

The Core Lab should be sent all reconstructed study data, including emission, CTAC or transmission data from the imaging day associated with each injection. It is requested these be provided in DICOM 3 format. In addition, the transmission (or CT) scan should be sent in DICOM format.

In keeping with regulatory requirements, it is critical that no subject names or other identifying information (i.e. date of birth) be associated with the transferred image files. Files should be identified on the basis of the subject's randomization number (as described in the protocol) according to the algorithm described below.

5.2 File Naming Procedures

It is very important that each image center uses standard file identification so that all scans can be easily identified. The subject ID will be provided by the Clinical Study Coordinator at the clinical site prior to the PET visit. The subject ID will be utilized in the naming convention for each PET scan.

Please note: The site number is assigned to the clinical sites in the trial, not the imaging centers.

The naming is as follows:

- XXX-XXXX 3 digits clinical site number- 4 digit subject ID.

- The files will need to be specifically named to designate the site, subject, and scan visit number.
 - Screening = 1
 - Visit 4 (month 12) = 2
 - Visit 6 (month 24) = 3
 - Visit 10 (month 48) = 4
 - Premature Withdrawal = 5

Cameras that acquire in static mode: (2 individual PET files + 2 individual transmission or emission scans):

- If your camera acquires static scans the following convention should be used:

Site code - Subject number- Scan visit number.

Below is the code for the scan visit number:

- Example: For a screening (first scan) of subject 1001 from site 034, that has a PET/CT machine and acquires the CT image prior to the emission scans, the Patient Name and ID can be named as follows:

034-1001- 1

Series description fields should be EM50 for the 50 min post injection series and EM80 for the 80 minute post injection series and CT for emission and CT scans respectively.

- Example: For a Visit 4 (month 12) scan of subject 4567 from site 222 which has a PET scanner that acquires a transmission scan after the emission scans, The Patient Name and ID would be named as follows:

222-4567- 2

Series description fields should be EM50 for the 50 min post injection series and EM80 for the 80 minute post injection series and CT for emission and CT scans respectively

Cameras that acquire in dynamic mode (4 individual PET files + 2 individual transmission or emission scans):

- If your camera acquires dynamic scans (1 study with 2 series in each. One series being the CT or transmission scan and the second

being the 2 x5 min frames of the emission scan 50 – 65 min post injection.), the following convention should be used:

Site code - Subject number - Scan visit number – series number

- Example: For a screening of subject 2231 from site 111 , that has a PET/CT machine, emission and transmission image files would have the following nomenclature:

111-2231-1-01 Transmission or CT scan

Series description field should be TX or CT

111-2231-1-02 50 - 55 minutes post-injection

Series description field should be EM50

111-2231-1-03 55 – 60 minutes post-injection

Series description field should be EM55

111-2231-1-04 Transmission or CT scan

Series description field should be TX or CT

111-2231-1-05 80 – 85 minutes post-injection

Series description field should be EM80

111-2231-1-06 85 – 90 minutes post-injection

Series description field should be EM85

- Example: For a Visit 4 (month 12) scan of subject 4567 from site 222, which has a PET scanner that acquires a transmission scan after the emission scans, emission and transmission image files would have the following nomenclature:

222-4567-2-01 50 - 55 minutes post-injection

Series description field should be EM50

222-4567-2-02 55 – 60 minutes post-injection

Series description field should be EM55

222-4567-2-03 Transmission or CT scan

Series description field should be TX or CT

222-4567-2-04 80 – 85 minutes post-injection

Series description field should be EM80

222-4567-2-05 85 – 90 minutes post-injection

Series description field should be EM85

222-4567-2-06 Transmission or CT scan

Series description field should be TX or CT

5.3 Study Data Archiving

Imaging centers are required to archive the reconstructed imaging data for this study as this is considered to be the source data. Additionally and if possible, raw (sinogram) data should be archived as well. The method of archiving should follow the imaging center's specific Standard Operating Procedures.

NOTE: If your center does not have the capability to archive the reconstructed imaging data or raw (sinogram) data, please inform IND as soon as possible.

Also, all study related source documentation should be maintained in the appropriate section of the Technical Binder. All queries and/or correspondence will also need to be maintained and filed in the Technical Binder. All study documentation and PET data must be retained by the imaging center in accordance with the protocol.

6.0 Adverse Events

An adverse event is defined by the FDA as –

“Any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure that occurs during the course of the study.”

In this trial, the Clinical Study Site Investigator is responsible for reporting adverse events (AEs). Although adverse events related to the PET imaging ligands themselves are rare, other things can happen

during the subject's time at the PET center (i.e. subject falls, injection site reaction, nausea, dizziness, etc.).

Therefore, it is very important for the imaging centers to contact the clinical study site personnel immediately (i.e., Principal Investigator or study coordinator) if they become aware of any adverse events during the imaging procedures. The clinical coordinator should be contacted by phone and then a follow-up should occur in writing (by fax or e-mail).

If the event is a Serious Adverse Event (i.e., an adverse event that results in one of the following outcomes: death, initial or prolonged inpatient hospitalization, a life-threatening experience (that is, immediate risk of dying), persistent or significant disability/incapacity, congenital anomaly/birth defect, being considered significant by the investigator for any other reason) this needs to be reported to the clinical investigator immediately, as the clinical investigator has a duty to report this to the Sponsor within 24 hours.

7.0 Data Transfer

All image data transfer is by secure file transfer protocol (sFTP) or Direct DICOM transfer to the IND servers in New Haven, CT. Individual imaging center issues regarding transfer of imaging data will be addressed at the technical site visit. The preferred method is via direct DICOM transfer.

Each imaging center will be provided an sFTP address and login code during the Test Data Transfer process (see Section 2.2). If necessary, the IND staff will assist the imaging center in the implementation of sFTP client software or in setting up a direct DICOM transfer. It is requested that image files be sent in DICOM 3 format, if possible. Specifics of the file format will be worked out during the technical site visit before first subject enrollment. In circumstances where it is not possible for imaging centers to send data to IND via sFTP or direct DICOM transfer, IND will accept data on CD or DVD. It should be sent to IND labeled with the protocol name, site number, site name, subject ID, and acquisition date.

Please note: Imaging centers that are sending IND images for more than one study protocol will have a separate sFTP username and password for each study. It is important for the

image center to use the right username and password when sending the data so that it can be parsed to the correct study.

Using the file naming procedures detailed in Section 5.2, the site should record the files to be sent on the PET Acquisition Document and PET Imaging Data Transfer Information Documents (Appendix 3 and Appendix 4). These sheets should be faxed to IND (fax number + 1 203-401-4303) along with the other documents requested (Dispensing Log and Camera QA Log). Once the PET data and corresponding acquisition documents are received at IND, the imaging center will be sent an email indicating that the data and documents have been received and that they are under review. This email should be printed and filed in the Technical Binder. The Core Lab will then review the file transfer document against what was received on the sFTP or DICOM server to check for the presence of all expected data files. Each image file will be reviewed for accuracy and completeness using a standard quality assurance procedure. If there is a problem with the data file sent, contact will be made by the Core Lab to the imaging center. 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.

7.1 Transmission of Screening PET Scan Data and Follow-Up Scans

7.1.1 Screening Scans (For Australian Centers Only)

Visual assessments of the screening 18F-AV-133 scans by two IND expert readers are being used to determine whether or not subjects are eligible to participate in the trial. Therefore, it is essential that data be transferred to IND within **24 hours** of acquisition as IND will need to inform the clinical study site of the visual assessment results in the timeliest manner. If the imaging center will not be able to send the data within 24 hours after acquisition, it is requested that you call IND at 203-401-4360 or email corelab@indd.org to alert us as to when the center will be sending the data.

Please note that the results of the visual assessments will be documented on a "PET Scan Visual Interpretation" report and

this report will only be provided to the clinical study site and not to the imaging center.

Upon IND receiving the subject imaging data and corresponding acquisition documents, IND will send the imaging center an email response confirming the data and documents were received for that subject. Screening scans will go through IND's standard QC process (see section 7.2). Upon the completion of QC, which will include reviewing the image files for accuracy and completeness using a standard quality assurance procedure (Figure 2), if follow-up with the imaging center is necessary (copying the clinical study site) an email will be sent for query notification and resolution. A copy of this email should be filed in the Technical Binder or study files along with the originals of the source documents. If there is a problem with the data file sent, a contact will be made by the Core Lab to the imaging center. 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.

7.1.2 Screening Scans (For Centers in the United States Only)

Visual assessments of the screening 18F-AV-133 scans by two IND expert readers are in addition to the SPECT DAT visual assessments and will not be used to determine whether or not subjects are eligible to participate in the trial.

7.1.3 Follow-up Scans

It is requested that the follow-up scans below be transmitted to IND within **24-48 hours** of acquisition:

- Screening
- Visit 4 (month 12)
- Visit 6 (month 24)
- Visit 10 (month 48)
- Premature Withdrawal

Sites will not receive visual interpretation reports for these scans. Imaging centers will, however, still receive email notification of the receipt of the imaging data and corresponding documents. If needed, follow-up with the imaging centers will be done for query resolution. A

copy of this email should be filed in the Technical Binder or study files along with originals of the study documents.

7.2 Quality Control/Quality Assurance Process at IND

Image files sent to the Core Lab will undergo a two step quality assurance check, including a review of the file naming, ensuring image headers are de-identified, check of total counts, energy windows, movement artifacts, reconstruction artifacts, timing of the acquisition relative to AV-133 injection, among other checks. If queries arise in the course of these QC checks the Core Lab will contact the designated imaging center person for resolution.

Figure 2 details the QC process used for reconstruction, attenuation correction, and development of an imaging reference set from the participating study sites.

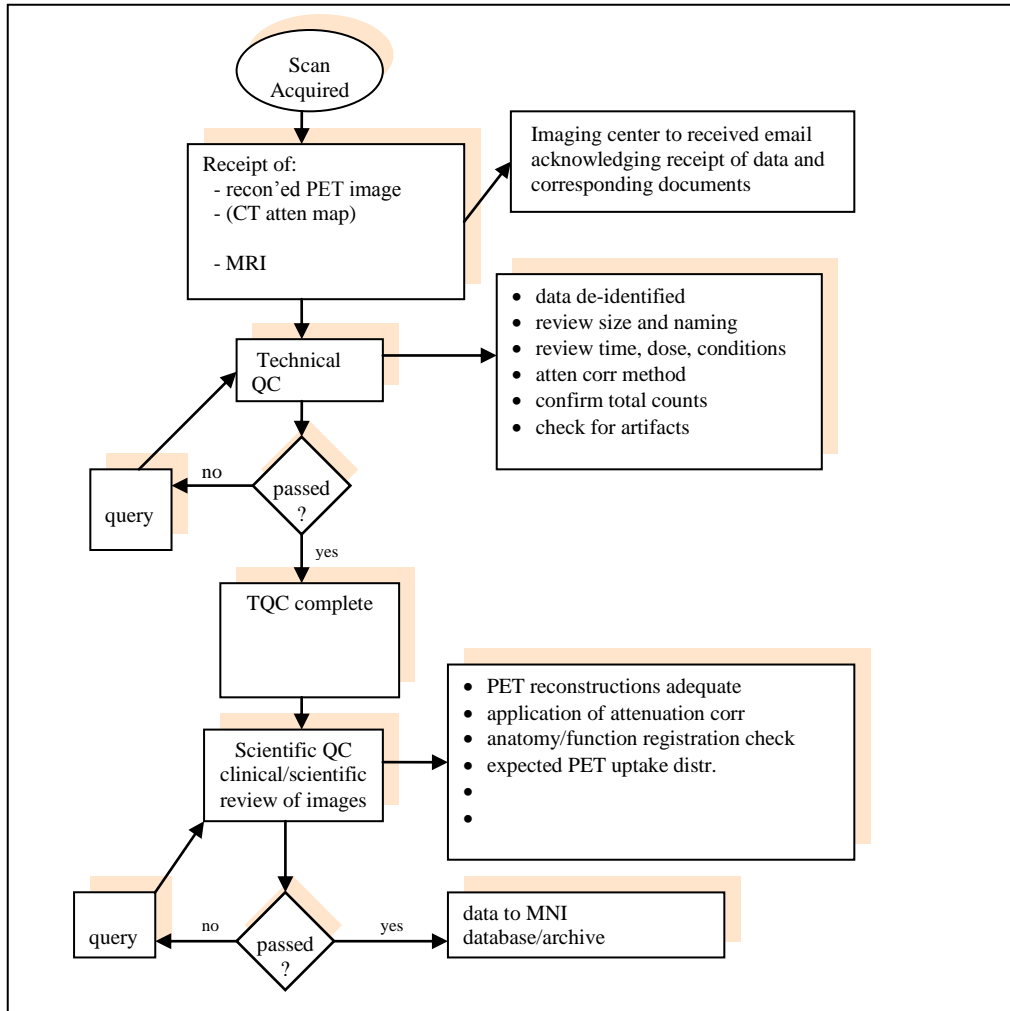


Figure 2: Core Lab QC Data Algorithm

The Core Lab algorithm for reconstruction, attenuation correction, and development of an imaging reference set from the participating study imaging centers.

8.0 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, scan documents, etc. In addition, the technical binder serves as a reference document for the imaging center summarizing all technical procedures for the study. The technical binder contains the following:

- Contact information
- Technical Operations Manual (a.k.a. Imaging Protocol)
- Study Protocol
- Camera QA Event Log forms
- Instructions for completion of Camera QA Log
- PET Acquisition Document
- sFTP server, user, and password information or DICOM push information
- PET Imaging Data Transfer Information Documents
- Dispensing Log for Clinical Supplies Documents
- AV-133 dose ordering documents
- Avid Radiopharmaceutical's "*Avid Clinical Supplies Guidance Document*"
- Investigator's Brochure
- Adverse Event Reporting Fax Sheets
- 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 imaging center prior to the technical site set-up visit, along with instructions for maintenance of the technical source documents.

Note: It may be necessary for IND to update documents during the course of the trial. A copy of all versions of documents provided by IND should be kept in the Technical Binder, although the most recent version of any form should be used for subject scans. Also, many imaging centers will be participating in several trials with IND. It is critically important for the imaging center to use the right forms for each trial. IND will not accept data recorded for a subject in one trial on the forms that should be used for another trial.

9.0 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. Upon receipt of the data and corresponding documents, IND will notify the imaging center of the receipt via email. All imaging data will be reviewed and if no issues are found, this email will be the only notification the center will receive. If there are issues found, a query(ies) will be generated and returned to the imaging

center for resolution. Queries related to screening scans should be resolved and returned to IND within 24 hours of receipt; queries on follow-up scans should be resolved and returned to IND within 48 hours of receipt. Any queries with the data will be directed to the Nuclear Medicine group at the imaging center based on discussion and contact trees provided on the Site Questionnaire or 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.

The Institute for Neurodegenerative Disorders

60 Temple Street, Suite 8A
New Haven, Connecticut 06510

For all technical questions, camera, image processing, file-naming, file transfer contact:

Gary Wisniewski, CNMT
Director of Imaging Services

Telephone: 203-401-4311

Fax : 203-401-4303

Email: gwisniewski@indd.org

For questions concerning completion of the forms, or if you need more supplies, please contact:

Katrina Miles
Data Coordinator

Telephone: 203-401-4343

Fax: 203-401-4303

E-mail: kmiles@indd.org

Additional contacts :

Susan Mendick
Director, Clinical Imaging
Programs Management

Telephone: 203-401-4337

Fax: 203-401-4303

Email: smendick@indd.org

George Zubal, PhD
Director, Imaging Sciences

Telephone: 203 401 4355

Fax: 203-401-4303

Email: gzubal@indd.org


John Seibyl, MD
Director, Nuclear Medicine

Telephone: 203 401 4300

Fax: 203-401-4301

Email: jseibyl@indd.org

Appendix 1 Test Data Instructions and Test Data Transfer Document



PET Studies -
Site Instructions for Electronically Transferring
Test Data to the Core Lab

The IND Core Lab requires that sites successfully complete some preliminary tasks prior to scheduling a site set up visit. These tasks involve establishing the ability to electronically transfer a de-identified subject PET brain scan to the IND Core Lab via DICOM push, FTP or sFTP (secure shell). DICOM transfer is the preferred method.

Please note: test data needs to be sent using the same exact pathway anticipated to send subject data. For example, if subject data will be sent to a PACS system before being sent to IND, the test data transfer should occur using the same path to transfer the data.

Test Data Acquisition:

- Please provide a de-identified (no subject-identifying information such as name, age, gender, etc.) PET brain scan acquired using the standard brain acquisition protocol used at your center (transmission scanning is not required for this scan).

Test Data processing:

- The study should be reconstructed using the site's standard "preferred" reconstruction parameters (attenuation correction is not required).
- All files reconstructed, should be converted to DICOM if possible.
- Native files from your camera system (if possible) and DICOM files should be sent to the IND Core Lab electronically
- Please label the PET study file with the study protocol number [- your site name - and the term "Test Data". Example: **ABCCOMPANY 123-456-XYZIMAGINGCENTER-TESTDATA**

Test Data Transfer to IND:
 The preferred method of data transfer to the IND Core Lab is via direct DICOM transfer. However, if this is not possible, we ask sites to send us data via FTP or sFTP. As a method of last resort, if your site is unable to send data electronically, we will accept data on CD or DVD.

1. Direct DICOM Transfer (DICOM node to DICOM node):

a) Prior to trying to transfer data via direct DICOM push, we will need you to provide the following information to us so that our DICOM server can be set-up to receive your data:

- **Server IP Address:**
- **AE Title =**
- **Port:**

We ask that you send this information via e-mail identifying your site and the study in the e-mail to Sarah Whiteley at the IND Core Lab at: swhiteley@indd.org. Information about IND's DICOM Server that you will need to transfer the data to us via DICOM transfer can be found below

- **Server IP = pacs.mnimaging.com or **12.187.43.48****
- **AET = OSIRIX_MNI**
- **Port = 4096**

b) Fill out the PET Test Data Transfer Information Document provided. All fields should be completed. If they do not apply, (i.e. transmission scan not done) please enter N/A in the appropriate field.

c) FAX the completed the PET Test Data Transfer Information Document to Core Lab at 203-401-4303. Completed documents may also be emailed to IPAD@mnimaging.com.

2. Sending Test Data via FTP or sFTP Transfer:

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V 1.0PPMAV133
15.March.2012



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PROGRESSION
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INITIATIVE
Project P-001 - 00000000000000000000

PET Studies -

Site Instructions for Electronically Transferring Test Data to the Core Lab

- a) Native files or DICOM files can be sent via FTP or preferably SFTP to Core Lab server:
ftp.mnimaging.com or **12.187.43.39**. For FTP or SFTP transfer, a username and password will be provided to you by IND (will be provided in a separate email).
- b) Fill out the PET Test Data Transfer Information Document provided. All fields should be completed. If they do not apply, (i.e. transmission scan not done) please enter N/A in the appropriate field.
- c) FAX the completed the PET Test Data Transfer Information Document to Core Lab at 203-401-4303. Completed documents may also be emailed to IPAD@mnimaging.com.

3. In the event that electronic test data cannot be electronically transferred to IND:

In the event that it is impossible to electronically transfer data to Core Lab, it may be possible to make other arrangements such as sending the test data on CD or DVD via overnight courier. For FTP or SFTP transfer, a username and password will be provided to you by IND (will be provided in a separate email).

- a) Load the test data scan onto a CD or DVD, preferable in Native files or DICOM format. Label the CD or DVD with the name of the study your site name and the words "TEST DATA".
- b) Fill out the PET Test Data Transfer Information Source Document provided. All fields should be completed. If they do not apply, (i.e. transmission scan not done) please enter N/A in the appropriate field.
- c) Please send the CD or DVD with the PET Test Data Transfer Information Document to:

The Institute for Neurodegenerative Disorders
c/o: Core Lab
60 Temple St., Suite 8B
Suite 8B
New Haven, CT 06511

Core Lab Follow-up

Once the transferred files and documents are received at Core Lab, we will confirm receipt within 1 business day. Core Lab will then perform QC on the data that is sent. Barring no issues, the QC should be completed within 2 business days of receipt and a confirmation of acceptance will be sent back to the site within 3 business days. If there are any issues, then a query (Data Clarification Form) will be generated and submitted to your site for clarification. Any issues will need to be resolved prior to acceptance of the data and the subsequent scheduling of the Technical Site Visit. These issues may involve, but are not necessarily limited to technical problems with the data or problems in file transfer.

If there needs to be another arrangement, it would also need to be established, tested and in place prior to the set up visit.

If you need assistance in any aspect of this request please contact either your IND project manager or project associate.

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IND

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V 1.0PPMAV133
15.March.2012

PET Test Data Transfer Information Document				PPMI AV-133	
Site Number:	<div style="background-color: black; width: 40px; height: 15px;"></div>			Scan Acquisition Date:	
					DD / MON / YYYY
Imaging Center Name: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Type of Acquisition	<input type="checkbox"/> brain	<input type="checkbox"/> point source	<input type="checkbox"/> other	File Format:	<input type="checkbox"/> DICOM <input type="checkbox"/> Other: <div style="border: 1px solid black; width: 80px; height: 20px;"></div>
Transfer Mode:	<input type="checkbox"/> DICOM Transfer <input type="checkbox"/> sFTP <input type="checkbox"/> CD or DVD <input type="checkbox"/> Other: <div style="border: 1px solid black; width: 180px; height: 20px;"></div>				
Data Format:	<input type="checkbox"/> DICOM <input type="checkbox"/> Interfile <input type="checkbox"/> Native System File <input type="checkbox"/> Other: <div style="border: 1px solid black; width: 150px; height: 20px;"></div>				
Camera:	<div style="border: 1px solid black; width: 250px; height: 20px;"></div>				
Reconstruction Method:	<input type="checkbox"/> FBP <input type="checkbox"/> Iterative				
Attenuation Correction:	<input type="checkbox"/> CT Scan <input type="checkbox"/> Isotope Transmission				
<p>Please provide details of the pathway used to send the data (i.e. – Was it sent from the camera itself? Was it sent from the camera to another workstation and then sent? Was it sent to a PACS system and through a de-identification program before sending? Is it de-identified and then sent to a PACS system before sending?)</p>					
Details of Data Pathway to IND:					
Scans Sent:					
<input type="checkbox"/> CT Scan/ Transmission Reconstruction			Number of Slices: <div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
<input type="checkbox"/> Emission Reconstruction			Number of Frames: <div style="border: 1px solid black; width: 120px; height: 20px;"></div>	Number of Slices/Frame Transferred: <div style="border: 1px solid black; width: 60px; height: 20px;"></div>	
Date Data Sent to IND	<div style="border: 1px solid black; width: 30px; height: 20px;"></div>	/	<div style="border: 1px solid black; width: 30px; height: 20px;"></div>	/	<div style="border: 1px solid black; width: 30px; height: 20px;"></div>
	DD		MON		YYYY
Transfer Time (24-hr clock):	<div style="border: 1px solid black; width: 30px; height: 20px;"></div>	:	<div style="border: 1px solid black; width: 30px; height: 20px;"></div>		
	HH		MM		
Files Verified/Transferred by: <div style="border: 1px solid black; width: 370px; height: 20px;"></div>					
Comments:					
Please fax to IND at 203-401-4303 or e-mail to corelab@indd.org*					
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**PARKINSON'S
DIAGNOSIS KEYLINE
MARKERS
INITIATIVE**

PPMI AV-133

Imaging Site Name:	
Camera:	

[illegible][illegible]

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V 1 PPMI AV-133 08/Nov/2011

PPMI AV-133 Technical Operations Manual
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V1.2 12.July.2012

Appendix 3: Example of PET Acquisition Document*

<div style="display: inline-block; vertical-align: middle; font-size: 8px; margin-left: 5px;"> NATIONAL ALZHEIMER COORDINATING CENTER PET COORDINATING CENTER UNIVERSITY OF CALIFORNIA SAN FRANCISCO </div>		<h2 style="margin: 0;">PET Acquisition Document</h2>		PPMI AV-133	
Site Number: <input type="text"/> <input type="text"/> <input type="text"/>		Subject Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Scan Acquisition Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Imaging Center Name: <input style="width: 150px;" type="text"/>		Clinical Site Name: <input style="width: 150px;" type="text"/>			
Scan Number: <input type="checkbox"/> Screening <input type="checkbox"/> Month 12/Visit 4 <input type="checkbox"/> Month 24/Visit 6 <input type="checkbox"/> Month 48/Visit 10 <input type="checkbox"/> Premature Withdrawal					
		Weight (kg): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
18F-AV-133 Injection Information					
Batch Number: <input style="width: 100px;" type="text"/>		Injection Site: <input style="width: 150px;" type="text"/>			
Passed QC: <input type="checkbox"/> Yes <input type="checkbox"/> No					
Expiration Date & Time*: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
Volume of Injection (ml): <input style="width: 50px;" type="text"/>		Activity in Syringe Prior to Injection: <input style="width: 50px;" type="text"/>		<input type="checkbox"/> mCi <input type="checkbox"/> MBq	
<small>Note: Protocol calls for an injected dose of 6 mCi ± 10%. Please do not calculate decay correction when recording dose.</small>		Activity in Syringe After Injection: <input style="width: 50px;" type="text"/>		<input type="checkbox"/> mCi <input type="checkbox"/> MBq	
				Time Measured*: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
				Time of Injection*: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
Imaging Protocol Parameters:					
Use the same clock to document injection and scan times.					
Recon Filter Type (e.g. Gaussian, All-pass...): <input style="width: 100px;" type="text"/>		Camera: <input style="width: 150px;" type="text"/>			
Kernel (FWHM): <input style="width: 50px;" type="text"/>		Iterations: <input style="width: 50px;" type="text"/>		Subsets: <input style="width: 50px;" type="text"/>	
SCAN Session A—50 min. Post Injection					
CT/Transmission Scan Series Description: <input style="width: 50px;" type="text"/> - <input style="width: 50px;" type="text"/>					
<small>In this format: Site# - Subject # (e.g. 123-1230)</small>					
CT/Transmission Scan Start Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>		Stop Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
Emission Series Description(s)*: <input style="width: 100px;" type="text"/>					
<small>In this format: Site# - Subject # (e.g. 123-1230)</small>					
Start Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>		Stop Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
SCAN Session B—80 min. Post Injection					
CT/Transmission Scan Series Description: <input style="width: 50px;" type="text"/> - <input style="width: 50px;" type="text"/>					
<small>In this format: Site# - Subject # (e.g. 123-1230)</small>					
CT/Transmission Scan Start Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>		Stop Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
Emission Series Description(s)*: <input style="width: 100px;" type="text"/>					
<small>In this format: Site# - Subject # (e.g. 123-1230)</small>					
Start Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>		Stop Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
TECHNICAL COMMENTS:					
**Please fax to IND at +1-203-401-4303 or email to corelab@indd.org **					
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***refer to Technical Binder for Actual Study Documents**

Appendix 4: PET Imaging Data Transfer Document*

 PPMI <small>Partnership for Parkinson's Program Imaging Initiative</small>		PET Imaging Data Transfer Document		PPMI AV-133	
Site Number	<input type="text"/>	Subject Number	<input type="text"/>	Scan Acquisition Date	<input type="text"/> DD <input type="text"/> MON <input type="text"/> YEAR
Imaging Center Name:			Clinical Site Name:		
Scan Number: <input type="checkbox"/> Screening <input type="checkbox"/> Month 12/Visit 4 <input type="checkbox"/> Month 24/Visit 6 <input type="checkbox"/> Month 48/Visit 10 <input type="checkbox"/> Premature Withdrawal					
Transfer Mode: <input type="checkbox"/> DICOM Transfer <input type="checkbox"/> sFTP <input type="checkbox"/> CD or DVD <input type="checkbox"/> Other: <input type="text"/>					
Data Format: <input type="checkbox"/> DICOM <input type="checkbox"/> Interfile <input type="checkbox"/> Native System File <input type="checkbox"/> Other: <input type="text"/>					
SCANS SENT—Session A (50 minutes Post Injection):					
<input type="checkbox"/> CT Scan/Transmission Reconstruction					
<input type="checkbox"/> Emission Reconstruction					
SCANS SENT—Session B (80 minutes Post Injection):					
<input type="checkbox"/> CT Scan/Transmission Reconstruction					
<input type="checkbox"/> Emission Reconstruction					
Date Data Sent to IND:		<input type="text"/> DD <input type="text"/> MON <input type="text"/> YEAR	Time Data Sent to IND (24 hour clock):		<input type="text"/> HH <input type="text"/> MM
Files Verified/Transferred By: <input type="text"/>					
Comments:					
Once the imaging day is finished, fax or email completed form to IND at +1-203-401-4303 or email to corelab@indd.org					
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***refer to Technical Binder for Actual Study Documents**

Appendix 5: Radiation License and Radiopharmaceutical Shipping Information Document



Radiation License and Radiopharmaceutical Shipping Information

Instructions

Please complete this form and attach a copy of the site Radioactive Materials License. Fax back completed form and license to: 203-401-4303. If you have any questions, please contact Susan Mendick at smendick@indd.org or 203-401-4337

Site Name:	
------------	--

Name of Authorized User:	
--------------------------	--

Address:	
----------	--

City:		State/ Province:		Country:		Postal Code:	
-------	--	---------------------	--	----------	--	-----------------	--

E-mail Address:	
-----------------	--

Phone #:	
----------	--

Fax #:	
--------	--

Name of Authorized Receiver:	
------------------------------	--

Address:	
----------	--

City:		State/ Province:		Country:		Postal Code:	
-------	--	---------------------	--	----------	--	-----------------	--

E-mail Address:	
-----------------	--

Phone #:	
----------	--

Fax #:	
--------	--

Radiopharmaceutical Shipping Address							
--------------------------------------	--	--	--	--	--	--	--

Address:	
----------	--

City:		State/ Province:		Country:		Postal Code:	
-------	--	---------------------	--	----------	--	-----------------	--

Is a copy of the NRC License attached?	<input type="checkbox"/> Yes <input type="checkbox"/> No
--	--

Name of Person Completing the Form:	
-------------------------------------	--

Phone Number:		Date:	
---------------	--	-------	--


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MNIID1002

MNIID1002
V 1.PPMI AV-133

***refer to Technical Binder for Actual Study Document**

Appendix 8: Avid Drug Request Form*



DOSE REQUEST FORM

To be completed by the site			
Date:		Protocol:	
Site:		Subject ID:	
Product:		Amount Requested (mCi):	
Scheduled Date of Imaging Session:		Calibration time:	
Clinical Contact Name / Email:			
Imaging Site Contact Name / Email:			
Imaging Site:			
RAM license #:		Amendment:	
Authorized User:			
Comments/ Details for Avid:			
Preparer Signature and date:			

Fax completed form back to Avid at 215-689-4804
(A confirmation receipt will be sent via Email to the clinical contact and imaging contact listed above)

To be completed by Avid Radiopharmaceuticals	
Date and Time Request Received:	
Signature of Receiver of Request:	
Shipment approved by:	

To be completed by Manufacturer:			
Drug Request Received by (Print Name):		Date Received:	
Signature:			
Dose Scheduled for Manufacturing:	<input type="checkbox"/> Yes <input type="checkbox"/> No (If no, provide reason in space below)		

Fax completed form back to Avid at 215-689-4804

Avid Ref #: _____
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Version 5.0 07Feb2012

***refer to Technical Binder for Actual Study Document**