

## **PPMI** Data

# Notes and guidance for the end-user regarding PPMI Data

Version 1.1

Date: March 2012

Please be informed that you are downloading an open and active data set and there may be subsequent updates and changes in the data set you receive. It is the end-users responsibility to understand and use PPMI data given the caveats to the data noted below.

**IMPORTANT NOTE:** It is the policy of the Parkinson's Progression Markers Initiative to make data available to investigators as quickly as possible. These data are not locked and therefore may change. Furthermore, some data elements within PPMI will change with disease progression. Some results may also change as new methods of analysis are implemented or new findings are incorporated into the study. Be aware of the limitations of these data prior to using them for scientific purposes and that future results may change as additional data become available.

In accordance with the data use and publication policy, all users have agreed to the use of "preliminary data" which will be posted in the PPMI database. In the event that a user downloads data from the PPMI database for the purposes of analysis and future publication, in the form of abstracts and/or publications, the user will note the version/date of the data download. Prior to submission of any material for publication the user has agreed to check the PPMI database to determine if updated data has been provided.

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## Purpose of this document

The purpose of this document is to provide the end-user with information that will assist them in using the PPMI Data. The intent of the information provided here is to address potential questions and provide additional clarify to the data. This information is to be used in conjunction with the PPMI study protocol, study specific technical manuals, and CRFs (<a href="www.ppmi-info.org">www.ppmi-info.org</a>). Information in this document will be updated as new data sets are added and as new information becomes known.

## Introduction

The Parkinson's Progression Marker Initiative (PPMI) study is a 5-year longitudinal study funded by The Michael J. Fox Foundation for Parkinson's Research (MJFF) and industry partners with the mission of identifying one or more biomarkers of Parkinson's disease progression, a critical step in the development of new and better treatments for PD.

Sharing PPMI data with the general scientific community is an objective established from the onset of the study, and is strongly supported by MJFF – the sponsor of PPMI – and the PPMI Steering Committee. De-identified data collected as part of the PPMI study is stored in a central study data repository at the Laboratory of Neuro Imaging (LONI) at UCLA.

Full and open access of all de-identified PPMI imaging and clinical data is available to individuals who register with the PPMI Data and Publications Committee (DPC) and agree to the conditions in the "PPMI Data Use Agreement" (www.ppmi-info.org/data) and who undergo limited screening by the DPC. Access rights and policy to PPMI biospecimens is outlined in the Procedure and Guidelines to Access Banked Biospecimens.

## **Study Overview**

The PPMI aims to recruit 400 de novo Parkinson disease and 200 healthy controls to participate in longitudinal assessments, brain imaging, clinical evaluation, and data and biospecimen collection. Eligible subjects who choose to participate will complete a series of test and assessments, including brain imaging as outlined the Schedule of Activities (SoA). The schedule of activities for all subject cohorts can be found in the study protocol (www.ppmi-info.org).

#### **Ancillary studies:**

The PPMI study was designed with the flexibility to incorporate new biomarker assessments throughout the life of the project. Investigators can propose ancillary studies by completing the form below. While we welcome novel proposals, the already substantial subject and investigator burden in PPMI will limit

the number and scope of the ancillary studies ultimately accepted for inclusion in PPMI.

Ancillary studies may include additional study assessments that involve all or a subset of PPMI participants. Proposals are accepted on a rolling basis and will be reviewed based on the following criteria: The scientific merit of the proposal; Value added to PPMI; Additional burden to the subject, clinical site and central administration of PPMI; and, feasibility within the PPMI timeline.

The table below provides a brief description of the ancillary studies which were incorporated into the PPMI study as well smaller studies where data is collected at select site due to expertise or equipment availability (ie DTI)

Protocol/ Study
Scans Without Evidence of Dopaminergic Degeneration (SWEDD) (additional subjects)
Diffusion Tensor Imaging (DTI) MRI
<u>Three Site Assessment of the Potential for Home Dexterity Monitoring in a PD Biomarker Study (TAP-PD)</u>
18-F-AV-133 imaging of VMAT-2 (Vesicular Monoamine Transporter )
US sites subject also complete DAT imaging
18-F-AV-133 imaging of VMAT-2 (Vesicular Monoamine Transporter )
AUS site/s (additional subjects)

Biologic sample request and assay data:

resting state Magnetic Resonance Imaging (rsMRI)

Cognitive Categorization

A critical component of PPMI is the standardized, longitudinal collection of biospecimens, which include plasma, serum, blood, cerebrospinal fluid (CSF), DNA and RNA. An inventory of the biospecimens is available through the PPMI database and can reviewed by investigators interested in incorporating PPMI samples in their research. Please note that PPMI samples can only be used for biomarker verification studies.

The PPMI Steering Committee has already identified preliminary analyses that will be conducted on the PPMI data by the study cores. The resulting data from these analysis and the method used to assay the samples will be available as part of the PPMI database.

## **Study Data Collection**

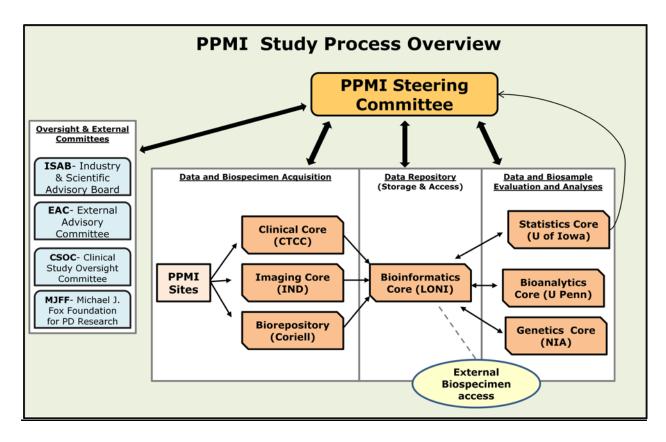
The PPMI study is comprised of neurological and movement disorder study sites throughout the Unites States (US) Europe (EU) and Australia (AUS), and study cores with expertise in clinical assessments, neurological imaging, biologic sample storage (biorepository), bioinformatics, statistics, bioanalytics and genetics. The PPMI dataset includes clinical assessments and evaluations, subject demographics, imaging data, and biological samples. The PPMI study governance and oversight includes a Steering Committee, a Clinical Study Oversight committee (CSOC), an External Scientific Advisory (ESA) an Industry and Scientific Advisory Board and the MJFF.

To reduce variability and ensure that data and samples are uniformly acquired, the PPMI study has established standardized protocols for acquisition, transfer, and analysis of clinical, imaging and biologic data, as well as biosample collection, processing and storage. Preceding site initiation, site personnel complete a training session to confirm that the site understands the standardized procedures and data and sample collection processes.

Clinical sites throughout the US and EU recruit subjects (400 de novo Parkinson disease - PD and 200 age and gender matched healthy control- HC), complete study evaluations, assessments and biosample collection as outlined in the PPMI protocol (See Schedule of Activities). The process by which subject data is collected and transferred to the central PPMI database at LONI, the Bioinformatics Core, is outlined in Figure 1. Briefly, the process in initiated at the clinical sites where subject assessments, evaluations, and clinical data are entered via the eClinical web-portal into the PPMI database at the Clinical Trial Coordination Center (CTCC- Clinical Core) at the University of Rochester. De-identified biological samples collected at each visit are shipped directly to the Biorepository Core at Coriell Institute for Medical Research (Camden NJ) or BioRep (Milan, Italy) for the EU sites. Upon receipt and inventorying of samples, the biorepository performs a set of defined QC procedures for all samples. The Coriell biosample inventory data is reconciled with the subject data at CTCC and transferred with the QC results to the PPMI central data repository at LONI.

As part of the inclusion criteria subjects undergo DaTSCAN imaging. Sites coordinate with PPMI approved imaging centers for all subjects to receive an MRI and a DaTSCAN. Scan data is sent to the Imaging Core at the Institute of Neurodegenerative Disorders (IND, New Haven, CT) for QC and visual evaluation of DAT deficit.

Following QC, evaluation of data, and reconciliation of data as outlined, all data is transferred on a regular schedule from the indicated cores to the PPMI database at LONI.



## **Study Data Evaluation and Analysis:**

Study data from the central data repository at LONI is provided the STATs Core at the University of Iowa for ongoing analysis and interim evaluations. On an ongoing basis, the STATs core provides study data tables to the PPMI SC and biannually to the CSOC for review. Data from the Bioinformatics Core and biospecimens from the Biorepository Core are transferred to the Bioanalytics Core at University of Pennsylvania (U Penn) and the Genetics Core at the National Institute of Aging (NIH/NIA) for defined analyses. Data generated from the Bioanalytics and Genetics Cores and assayed biosample results are incorporated into the PPMI data repository at LONI.

PPMI and Non-PPMI investigators can request access the PPMI data through the PPMI Data and Publications Committee (DPC). For access to the biospecimens, investigators will need to apply for access using the process described in the 'Procedure and Guidelines to Access Banked Biospecimens'. The PPMI Biospecimen Review Committee (BRC) conducts a 2-stage process to review and potentially accept a research proposal by an investigator/s. Following acceptance of proposal, the researcher will receive blinded biospecimens from the Coriell biorepository. When the analyses are completed the investigator will submit data to the PPMI database. The investigator will have 2 months from the time of submission to the PPMI website to view the un-blinded data to ensure proper quality control before the data is made publically available through the PPMI website.

## Clinical Data EDC and Query process at CTCC

After a subject visit occurs, clinical data is entered by sites (study coordinator or designee) into the CTCC database via the eClinical EDC system. Data for visit assessments is collected in the database as electronic pages (ePages). A visit (i.e. Screening, Baseline V-3) may be comprised of several sets of ePages. A series of real-time edit checks are generated as data entry occurs, prompting the coordinator to clarify or correct an entry. When the ePages are completed, saved, and marked "Entry Complete" by the site the data set then available for a nightly CTCC electronic edit check.

During the nightly edit checks, data are evaluated for accuracy and completeness. Inaccurate or missing values in a data set will generate a data query. The query is sent to the site's query management queue and the ePage is tagged as having an open query. All ePages marked as "Entry Complete" are now available for nightly transfer from CTCC to the LONI database. If a partial set of ePages is entered into the CTCC database it will also go through the nightly query process; however, the data will not be available for transfer to the LONI database until marked "Entry Complete" by the site.

When queried data is corrected or updated by the site coordinator the entire set of ePages is reprocessed through the nightly query process. If the query is resolved, the ePages are no longer flagged as having an open query. The updated data set without a 'query' flag is transferred to the LONI database replacing the previous data set. Data transfers occur between CTCC and LONI nightly.

## **Clinical Data Lock:**

For data to be locked the following process will occur:

- Specified key items in subject charts will be reviewed by a site monitor and determined to be accurate (a 100% QC of charts is not planned)
- Data sets from the monitored subject (site) will be provided by LONI
  to the statistic core for evaluation of outliers, anomalies, and
  consistency (i.e. the data looks like it should)
- Any questionable data will be queried and resolved
- Data will be reviewed by the PPMI data analysis committee
- When data is deemed "locked", LONI and CTCC or appropriate core will mark the data set as Locked

## **Query Status Categories:**

Data would be active or locked/ inactive. Active data may or may not have an outstanding query. Locked data has all queries resolved and has completed the QC process and is not expected to have any new queries. Active data is part of the continually acquired data stream. The data, which is actively deposited into the PPMI databases at CTCC and LONI will be susceptible to guery until it is Locked.

Table 1 outlines the 3 tiered identification system using the color code system and variables below were N=Null:

	Query Color	
QUERY*	Code	Description of data
\N or		
blank	Yellow	Active data with no outstanding queries at this time
Open	Red	Active data with outstanding queries
		Inactive/ locked data: data that has completed query
Locked	Green	and QC

<sup>\*</sup>As extracted from LONI database

#### Table 1: Query status of PPMI Data sets.

This is an on-going study and data is actively being added to the PPMI database, as a result there is a lag time between a subject being consented and the screening visit being marked complete. This is a result of the screening process were interested subjects complete a PPMI Screening Visit (SC), which includes signing informed consent (Consented), reviewing and completing the eligibility criteria, and the screening assessments. As part of the Screening visit, a subject will need to complete an MRI and a DaTSCAN which is only available on limited days. After ICF a site has 30 days to have the subject complete the DaTSCAN, MRI and all the screening assessments. Being an exclusion /inclusion criteria the DaTSCAN needs to be completed and evaluated before the Baseline assessments are started. If there are extenuating circumstances such as production failures of DaTSCAN this could be longer than 30 days and will require a waiver. Therefore it is possible that a subject could be entered in the CTCC database as consented (and the data transfers to LONI), but the entire Screening visit cannot be completed until the DaTSCAN imaging is completed, assessed at IND, and the 7 (+/- 3) days AE call is completed (see CRF #62).

## **Biospecimen Reconciliation:**

CTCC pulls the cumulative data set from Coriell nightly and the data is stored as part of the CTCC database (it is not entered via the eClinical system). CTCC reconciles the Coriell data set with the internal PPMI data by comparing the Coriell data to the data that was entered by the sites in the DNA, Lumbar Puncture and Laboratory pages. CTCC reports any discrepancies with the following:

- Invalid patient numbers in the Coriell data
- Wrong or mismatched visit names in the Coriell data
- Coriell is missing samples that have been documented in the CTCC eClinical system
- Coriell has received samples that were not documented in the CTCC eClinical system

After the data from Coriell is reconciled, that data set is available to LONI for the nightly transfers. CTCC will prevent data with invalid patient numbers from being included in the transfer. An "Invalid patient numbers" would include those cases where the site has not yet created the subject record in the CTCC eClinical system. At the current time, data is not being filtered based on the header checks.

## Notes on the Clinical Assessments and Data Sets:

For a list of decoded values and field values, refer to the Code List and Data Dictionary (downloadable) under Study Docs on the PPMI data web site. The raw data collected at the subject visit is available for download. In addition to the raw data several normalized or computed total scores are available. The computed scores and values are described in sections below.

Inclusion/Exclusion criteria for Parkinson disease and healthy controls contain overlapping criteria. The Inclusion/Exclusion data set contains the PD, HC and SWEDD inclusion (1-11) exclusion (1-15) criteria. Refer to the Inclusion/Exclusion CRF located under Study Docs on the PPMI data web site to determine mutual and diagnosis specific criteria.

#### Subject cohort category

This summary table identifies the category (PD, HC) that the subject was recruited as, and the subjects study category post DAT or VMAT2 imaging (PD, HC, SWEDD). If the subject was enrolled, the date the subject enrolled and the category the subject is enroll as (PD, HC, SWEDD) is included in the table as well as a column with the subjects current enrollment status.

#### Calculation of Subject Age at Enrollment (Baseline)

Date (Month & Year) of enrollment (enrollment date is from the field ENROLLDT which is from the Pag\_Name = RANDOM) minus the subject DOB (Month & Year) divided by 365.25 displayed as ##.# (years).

#### Calculation of Duration of Disease at Enrollment (Baseline):

Date (Month & Year) of enrollment (enrollment date is from the field ENROLLDT which is from the Pag\_Name = RANDOM) minus the date of diagnosis (Month & Year) from screening visit CRF #14, divided by 12 displayed as ##.# (months).

## Subject has family members with PD:

A response of 1 or greater to any question 1.2 through 9.2 on CRF #20. This CRF includes data on both first degree and non-first degree relatives.

## Notes on the Motor Assessments and Data Sets:

The PPMI central database at LONI contains the raw data for motor assessments completed at clinical visits. For the MDS-UPDRS assessments, both the raw data and sub-scores will be provided. The sub-scores and criteria for each of the MDS-UPDRS sections are also provided (Table 2). The PPMI Operations Manual contains more information on the administration of the subject assessments.

MDS-UPDRS Section	Sub-Score Calculation
MDS-UPDRS Part I	Sum the value of scores for 1.1 through 1.6
MDS-UPDRS Part I - Patient	
questionnaire	Sum the value of scores for 1.7 through 1.13
MDS-UPDRS Part II - Patient	
questionnaire	Sum the value of scores for 2.1 through 2.13
MDS-UPDRS Part III	Sum the value of scores for 3.1 through 3.18 OFF
MDS-UPDRS Part III	Meds Sum the value of scores for 3.1 through
(Post Dose - starts at VO4)	3.18 ON Meds
MDS-UPDRS Part IV	Sum the value of scores for 4.1 through 4.6
	Sum of Parts I-III: scores for 1.1 through 1.6,+
MDS-UPDRS Total	1.7 through 1.13, + 2.1 through 2.13, + 3.1
	through 3.18 OFF Meds

Table 2: Sub-score calculations of MD-UPDRS\*

For the data set MDS-UPDRS Part III (Post Dose) subjects taking Parkinson Medication at yearly visits 1-5 (V04, V06, V08, V10 & V12) will have 2 sets of MDS-UPDRS part III of data per visit. The first set of assessment data (prior to medication) will be displayed like any other time this assessment is done (i.e. SC or BL). The additional assessment, Post Dose, will appear as an additional row in the data set. To differentiate between the two assessments use the Page Name (which is the PAG\_NAME column) as shown below.

PAG_NAME	Data Set
NUPDRS3	MDS-UPDRS Part III assessment done prior to medication /in the OFF state
NUPDRS3A	MDS-UPDRS Part III assessment done Post Dose in the ON state

Additional information regarding the time that the dose was taken in clinic and the time the assessment was done (after the dose) is also captured in the NUPDRS3A data. The data from each assessment time will line up in the same columns.

## Notes on the Non-Motor Assessments and Data Sets:

The PPMI central database at LONI contains the raw data for the non-motor assessments completed at clinical visits.

## **Neuropsychological Tests:**

Table 3 list the Neuropsychological assessments where a cumulative score will also provided. The test or assessment and a brief description regarding data collection and comments are below. The PPMI Operations Manual contains more information on the administration of the subject assessments.

Neuropsychological Test or Assessment	Score Calculated	Score Calculation
Semantic Fluency	Calculate "Total Semantic Fluency Score"	Sum the value of scores for 1 through 3
Letter number sequencing	Calculate "Letter-Number Sequencing Total Raw Score"	Sum the value of scores for 1a. 1b. 1c. through 7a. 7b. 7c. (total will be between 0-21)

Table 3: Sub-score calculations of non-motor assessments

#### Hopkins Verbal Learning Test (HVLT) - Revised

For the Immediate Recall, Delayed Recall, and Delayed Recognition the total number of correct responses is recorded for each trial. The value for question 1.4 Delayed Recall Trial #4, reflects the correct number of responses after <u>approximately</u> 20 minutes delay

#### **HVLT Score Range:**

Immediate Recall: 0 - 12 for each Trial 1, 2, & 3.

Delayed Recall: 0 - 12

Delayed Recognition Hits: 0 - 12

Delayed Recognition False Alarms: 0 – 12

#### **Benton Judgment of Line Orientation**

Subjects are evaluated on 15 items per test period starting with the odd numbered items at the first test and the even numbers items at the second testing. For each item, record the subject's two response choices. Both responses must be correct for the item to be scored as correct.

Benton Judgment Line Orientation Score Range: 0 – 15

#### Semantic Fluency (Animal, Vegetables, Fruit)

Total number of *correct* unique animal, vegetable, or fruit names produced within 60 seconds.

<u>Semantic Fluency Score Range:</u> The scoring is liberal. Productivity is favored over semantic exactness.

#### **Letter Number Sequencing**

For each trial of an item (7 items total), a score 1 point is given for each correct response, 0 points for each incorrect response. A response is incorrect if a number or letter is omitted or if the numbers and letters are not said in the specified sequence.

<u>Letter Number Sequencing Score Range:</u> The highest score on an item is a total of 3 (i.e. 1 point each for 1a, 1b, 1c). Total Raw score range is 0 - 21

#### **Symbol Digit Modalities Test**

The score is the number of *correct* responses in 90 seconds.

<u>Symbol Digit Modalities Score Range</u>: 0 - 110

#### Montreal Cognitive Assessment (MoCA)

One point is added to the score for an individual who has 12 years or fewer of formal education. A subject can score a maximum of 30 points. Both the individual question scores and the total score, simple sum is available

MoCA Score Range: 0 - 30

#### **Neurobehavioral Tests:**

#### Geriatric Depression Scale (Short) - GDS-15

The GDS is scored centrally. The scoring rule is provided below: (NOTE: Some scores are in the opposite direction)

An answer of 0 = NO for CRF questions 1, 5, 7, 11, and 13 (indicate depression) 1 point is added to total score for each response of NO on these 5 questions

An answer of 1=YES for CRF questions 2,3,4,6,8,9,10,12,14,and 15 (indicate depression) 1 point is added to total score for each response of YES on these 10 questions

Note: A total of 12 questions need to be completed for the test to be considered valid.

#### Categories:

- 0 4 Normal depending on age, education, complaints
- 5 7 Mild depression
- 8 11 Moderate depression
- 12-15 Severe depression

#### **State-Trait Anxiety Inventory**

S-Anxiety or the T-Anxiety scale – To be provided

#### Questionnaire for Impulsive-Compulsive Disorders (QUIP-SHORT)

The QUIP is scored centrally. The scoring rule is provided below: For CRF#50 questions A1 through E3, an answer of 0= NO and an answer of 1=YES.

Question A-D (see below) address the 4 major impulsive compulsive disorders (ICD), question E addresses the 3 minor ICDs.

Short Instrument	Number of endorsed items for positive screen	Query title
A. Compulsive gambling	YES (1) to any 1 of the 2 gambling items	QUIP Positive-Gambling (n)
B. Compulsive sexual behavior	YES (1) any 1 of the 2 sexual behavior items	QUIP Positive-Sex (n)
C. Compulsive buying	YES (1) any 1 of the 2 buying items	QUIP Positive-Buying (n)
D. Compulsive eating	YES (1) any 1 of the 2 eating items	QUIP Positive-Eating (n)
E. Other Behaviors		
Hobbyism item #1	YES (1) to this question	QUIP Positive-Hobbies (n)
Punding item #2	YES (1) to this question	QUIP Positive-Punding (n)
Walkabout item #3	YES (1) to this question	QUIP Positive-Walking or driving (n)

#### Scoring:

0 points are added to score for each response of NO

1 point is added to the score for each response of Yes, for each guestion of the 4 major ICDs

- A score of 1 or greater is considered a positive ICD for each questions A-D

For question E, Other behaviors - a response of Yes (1) of each of the 3 minor ICD behaviors is considered a positive screen for that behavior

#### Scales for Outcomes in Parkinson's disease - Autonomic (SCOPA-AUT)

The SCOPA-AUT is scored centrally. The scoring rule is provided below:

There are 6 SCOPA subscales and a Total score:

Gastrointestinal – questions # 1-7

Urinary questions #8-13 (if they use a catheter, they get the highest score)

Cardiovascular -questions # 14-16

Thermoregulatory - questions # 17-20

Pupillomotor - question #21

Sexual - questions #22-23 if male or - questions #24-25 if female (Questions #23a and #26 do not contribute to the score)

**TOTAL SCORE** - simple sum of all responses from questions 1-23 if male (excluding question #23a) or 1-21 &24-25 if female (Because of the gender specific items, any respondent would do a total of 23 items)

Scores are all in the same direction ranging from: 0 = never to 3 = often

Response	Weight
never	0
sometimes	1
regularly	2
often	3

For the urinary questions #8-13, if a subject uses a catheter, they get the highest score (3) this response is coded in the database as "9" for these 6 questions,

For the sexual questions 22-23 if male or  $\,$  - questions # 24-25 if female, if a the questions non applicable no value is added to the score (ie 0) this response is coded in the database as "9" for these 4 questions.

#### **Epworth Sleepiness Scale (ESS)**

The score is the sum of weighted responses from questions 1-8, values (0-3).

Cut off for sleepy vs. not sleepy on the ESS: 9 or below is normal 10 or above is sleepy.

TOTAL SCORE: range: 0 - 24

#### **REM Sleep Behavior Disorder Questionnaire**

#### Scoring:

Questions 1-9 have a response of Yes or No. Question #10a-i one or more Yes or No responses

#### University of Pennsylvania Smell Identification Test UPSIT

This test contains 40 scent patches (scratch & sniff) to evaluate olfaction. The sent patches are arranged 1 per page, 10 scents per booklet, in 4 booklets. After release of the odorant a subject chooses from 1 of 4 options which best identifies the scent. The UPSIT raw score is the total number of scents identified correctly. This value is not normalized for subject gender or age.

UPSIT Raw Score Range: 0 - 40

## Notes on DaTSCAN and MRI data:

All subjects receive a DaTSCAN as part of the inclusion/exclusion criteria and subsequently as outlined in the Protocol (schedule of activities). SPECT scans from the PPMI Imaging sites are sent to the Imaging Core at IND for technical and scientific QC. Reconstructed SPECT scans received are visually assessed for evidence of dopamine transporter deficit. Two qualified readers assess each scan and their assessment must be in agreement. If the reader's assessments differ, the scan will be adjudicated and the agreed interpretation will be sent to the site. The results of the read are communicated to the PPMI recruiting site for inclusion or exclusion.

The reconstructed DaTSCAN scan images are transferred to the LONI database. For each subject the Imaging Core calculates Striatal Binding Ratios (SBR) values, which will be accessible from the PPMI database at

LONI. The DaTSCAN uptake is measured in the striata, relative to the DaTSCAN uptake in the occipital area. This ratio is referred to as the SBR, and is used for quantitating dopamine transporters in suspected parkinsonian syndromes.

DaTSCAN images and data for screen failures are transferred to the LONI Database as well.

At Baseline visit, all subjects will undergo a structural MRI. All subjects who complete an MRI will have a T-1 weight scan. If a T-2 weighted scan was also available, the Imaging Core will transfer both to the database at LONI. On occasion, a waiver may be given for subjects not completing an MRI.

## Notes on DTI Sub-study:

The PPMI Diffusion Tensor Imaging (DTI) sub study is preformed at approximately 8 PPMI imaging sites. The acquired DTI data completes a basic QC at the Imaging Core for transfer to LONI. DTI images evaluated for quality by Center for Imaging of Neurodegenerative Diseases (CIND) and processed images are uploaded the PPMI data website for download by authorized users.

## Notes on Non-protocol data sets:

Data obtained from biospecimen assays or analysis of the PPMI protocol data is also downloadable from the PPMI web site. This data is identified with a project number. Each project number contains an overview describing the meth of analysis used the investigator/s completing the analysis (for example hemoglobin analysis of the CSF samples evaluated).