PPMI

1 3 2 PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE) 0 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

PHYSICAL ACTIVITY SCALE FOR THE ELDERLY

(P A S E)

PPMI

1 3 2 **PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)** 0 0

SUBJECT ID | | | | | VISIT NO | | | |

New England
Research Institutes, Inc.

9 Galen Street
Watertown, MA 02472
(617) 923-7747

PPMI

1	3	2	PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)	0	0

SUBJECT ID | | | | | VISIT NO | | | |

INSTRUCTIONS:

Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:

During the past 7 days, how often have you seen the sun?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

Answer all items as accurately as possible. All information is strictly confidential.

1 3 2 **PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)** 0 0

SUBJECT ID _____ VISIT NO _____

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0.] NEVER → GO TO Q.#2

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

1a. What were these activities?

_____

1b. On average, how many hours per day did you engage in these sitting activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER → GO TO Q.#3

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

2a. On average, how many hours per day did you spend walking?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

1 3 2 **PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)** 0 0

SUBJECT ID | | | | | VISIT NO | | | |

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0.] NEVER → GO TO Q.#4 | [1.] SELDOM (1-2 DAYS) → | [2.] SOMETIMES (3-4 DAYS) → | [3.] OFTEN (5-7 DAYS) →

3a. What were these activities?

_____

3b. On average, how many hours per day did you engage in these light sport or recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0.] NEVER → GO TO Q.#5 | [1.] SELDOM (1-2 DAYS) → | [2.] SOMETIMES (3-4 DAYS) → | [3.] OFTEN (5-7 DAYS) →

4a. What were these activities?

_____

4b. On average, how many hours per day did you engage in these moderate sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

1 3 2 **PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)** 0 0

SUBJECT ID _____ VISIT NO _____

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0.] NEVER → GO TO Q.#6

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

5a. What were these activities?

_____

5b. On average, how many hours per day did you engage in these strenuous sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0.] NEVER → GO TO Q.#7

[1.] SELDOM (1-2 DAYS) →

[2.] SOMETIMES (3-4 DAYS) →

[3.] OFTEN (5-7 DAYS) →

6a. What were these activities?

_____

6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

[1.] NO [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

[1.] NO [2.] YES

9. During the past 7 days, did you engage in any of the following activities?

Please answer YES or NO for each item.

		NO	YES
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2
b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c.	Outdoor gardening	1	2
d.	Caring for an other person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_____ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

[1] Mainly sitting with slight arm movements. [**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.]

[2] Sitting or standing with some walking. [**Examples:** cashier, general office worker, light tool and machinery worker.]

[3] Walking, with some handling of materials generally weighing less than 50 pounds. [**Examples:** mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

[4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds. [**Examples:** lumberjack, stone mason, farm or general laborer.]

PPMI

1 3 2 PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE) 0 0

SUBJECT ID | | | | | VISIT NO | | | |

THANK YOU FOR TAKING THE TIME AND EFFORT

TO COMPLETE THIS QUESTIONNAIRE!

PPMI

1 3 2 **SCREENING/DEMOGRAPHICS** 0 2

SUBJECT ID [ ][ ][ ][ ] SITE NO [ ][ ][ ]

Complete one form for each subject who has signed consent and is potentially eligible to participate in the study.

A. ☐ Check box if subject has signed consent

B. Date informed consent was signed: B. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

C. Indicate the category for this subject: C. [ ]
(1 = Parkinson disease, 2 = Healthy Control, 3 = SWEDD, 4 = Prodromal)

C1. If Question C = 4, indicate the primary group type: C1. [ ]
(1 = Hyposmia, 2 = RBD, 3 = LRRK2)

1. Date of birth: 1. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

2. Gender (0 = Female of child bearing potential, 1 = Female of non-child bearing potential, 2 = Male) 2. [ ]

Women who are surgically sterile (hysterectomy or tubal ligation) or post-menopausal (last menstruation was 1 year or more prior to Screening Visit) are considered to be of non-child-bearing potential.

ETHNICITY

3. Do you identify your ethnicity as being Hispanic or Latino (Spanish origin)? 3. [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

RACE

4.1 Do you identify yourself as being American Indian or Alaska Native? 4.1 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.2 Do you identify yourself as being Asian? 4.2 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.3 Do you identify yourself as being Black or African American? 4.3 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.4 Do you identify yourself as being Native Hawaiian or Other Pacific Islander? 4.4 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.5 Do you identify yourself as being White? 4.5 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.6 Do you identify yourself with a race category not specified on this form? 4.6 [ ]
(0 = No, 1 = Yes, 2 = Unknown or not reported)
If Yes, please specify: _____

SUBJECT ID | | | | | SITE NO | | | |

5. Projected Enrollment Date: 5. MM DD YYYY

6. Referral Source: 6.

01 = Site personnel
02 = PCP
04 = Family or Friend
10 = Newspaper/ Magazine Article
11 = Newspaper/ Magazine Ad
14 = Radio/TV Ad
15 = Radio/TV Story
16 = Online News/ Blog/Other
17 = Out of Home Ad
18 = Event
30 = Advocacy Organization
31 = Support Group
50 = Study Website
53 = Site Website
54 = Study Web Ad
58 = Clinicaltrials.gov
59 = PDtrials.org
60 = Specialist
71 = MJFF Communication
72 = Another PD Subject
73 = Fox Trial Finder
80 = 1-800 Call center
99 = Other (specify in comments)

6a. If referred by a medical professional (02, 60), provide name:

_____

☐ 7a. Declined

7b. Reason for declining: 7b.

01 = Confidentiality issues
03 = Protocol too restrictive
04 = Protocol too time intensive
05 = Travel requirements
06 = Family advised declining
07 = Physician advised declining
08 = Enrolled in other study
09 = Not interested (specify in comments)
11 = Risks of Protocol
12 = Did not agree to lumbar puncture
99 = Other (specify in comments)

☐ 8a. Excluded

8b. Reason for exclusion: 8b.

01 = Exclusionary medication
02 = Other medical, psychiatric, or surgical condition
03 = Disease too advanced
04 = Dx uncertain
06 = Did not meet other inclusion criteria (specify in comments)
08 = Enrolled in other study
12 = Abnormal Safety Labs
13 = SPECT Scan
99 = Other (specify in comments)

Comments:

_____

_____

PPMI

1 3 2 **SOCIO-ECONOMICS** 0 4

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. Subject Education (number of years) 1. | |

4. Handedness (1 = Right, 2 = Left, 3 = Mixed) 4. |

PPMI

1 3 2 **CTCC UNIQUE ID** 0 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. CTCC 9 digit Unique ID: 1. | | | | - | | | | - | | | |

If you have previously generated a Unique ID for this subject and have it on file, please enter it from your records.

If you have not yet generated a Unique ID for this subject, please go to the following website to do so: https://www.ctcc.rochester.edu/uniqueid

If you have previously generated a Unique ID for this subject, and do not have it on file, you can go to the website to reconstruct it. Please note - you will need to enter the information exactly as it was entered before to recreate the same Unique ID.

PPMI

1 3 2 **INCLUSION/EXCLUSION - PARKINSON DISEASE (Amend 4)** 1 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Subjects must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia. 1. ☐

2. A diagnosis of Parkinson disease for 2 years or less at Screening. 2. ☐

3. Hoehn and Yahr Stage I or II at Baseline. 3. ☐

4. Not expected to require PD medication within at least 6 months from Baseline. 4. ☐

5. Male or female age 30 years or older at time of PD diagnosis. 5. ☐

6. Confirmation from imaging core that screening dopamine transporter SPECT scan is consistent with dopamine transporter deficit (or for sites only conducting PET scan that VMAT-2 PET scan is consistent with VMAT deficit). 6. ☐

7. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 7. ☐

8. Willing and able to comply with scheduled visits, required study procedures and laboratory tests. 8. ☐

9. Women may not be pregnant, lactating or planning pregnancy during the course of the study. 9. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-8 must be **1 = Yes** and item 9 must be **1 = Yes** if female of child bearing potential

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g., Wilson's disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy). 1. ☐

2. Currently taking levodopa, dopamine agonists, MAO-B inhibitors, (e.g. selegiline, rasagiline) amantadine or other PD medication. 2. ☐

SUBJECT ID | | | | | VISIT NO | | | |

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes) Continued

3.	Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline.	3.
4.	Has taken levopdopa or dopamine agonists prior to Baseline for more than a total of 60 days.	4.
5.	A clinical diagnosis of dementia as determined by the investigator.	5.
6.	Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening.	6.
7.	Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture.	7.
8.	Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia.	8.
9.	Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.	9.
10.	Use of investigational drugs or devices within 60 days prior to Baseline (dietary supplements taken outside of a clinical trial are not exclusionary, e.g., coenzyme Q10).	10.
11.	Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator).	11.

To be **ELIGIBLE** for study participation **ALL** answers to items 1-11 must be **0 = No**

To discuss questionable subject eligibility, call the CTCC Project Manager.

PROTOCOL DEVIATION CODE

PPMI
INCLUSION/EXCLUSION - PRODROMAL (Amend 8)

1 3 2 | 1 0

SUBJECT ID | VISIT NO

INITIALS | SITE NO | VISIT DATE (MM DD YYYY)

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

6. Confirmation from imaging core that screening dopamine transporter SPECT scan (or V-MAT-2 PET scan for sites where DaTSCAN is not available) is read as eligible. 6. ☐

7. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 7. ☐

8. Willing and able to comply with scheduled visits, required study procedures and laboratory tests. 8. ☐

9. Women may not be pregnant, lactating or planning pregnancy during the course of the study. 9. ☐

12. Male or female age 60 years or older. 12. ☐

13. Subject has at least one of the following characteristics: 13. ☐

a.) Confirmation from olfactory core that olfaction as determined by UPSIT is at or below the 10th percentile by age and gender

b.) Confirmation from sleep core that subject's Polysomnography meets criteria for RBD and/or clinical diagnosis of RBD by site investigator including existing PSG

To be **ELIGIBLE** for study participation **ALL** answers to items 6 - 8 and 12 - 13 must be **1 = Yes,** and item 9 must be **1 = Yes** if female of child bearing potential

PPMI
INCLUSION/EXCLUSION - PRODROMAL (Amend 8)

SUBJECT ID | | | | | | VISIT NO | | | |

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

5.	A clinical diagnosis of dementia as determined by the investigator.	5.
6.	Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening.	6.
7.	Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture.	7.
8.	Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia.	8.
9.	Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.	9.
10.	Use of investigational drugs or devices within 60 days prior to Baseline (dietary supplements taken outside of a clinical trial are not exclusionary, e.g., coenzyme Q10).	10.
11.	Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator).	11.
16.	Current or active clinically significant neurological disorder or psychiatric disorder (in the opinion of the Investigator).	16.
17.	GDS score greater than or equal to 10, or GDS score of 5 - 9 without Investigator discretion to enter study.	17.
18.	STAI Form Y-1 greater than or equal to 54 without Investigator discretion to enter study.	18.
19.	A clinical diagnosis of Parkinson disease at the Screening visit as determined by the Investigator.	19.

To be **ELIGIBLE** for study participation **ALL** answers to items 5 -11 and 16 - 19 must be **0 = No**

PPMI

1 3 2 **INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)** 1 1

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

7. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 7. ☐

8. Willing and able to comply with scheduled visits, required study procedures and laboratory tests. 8. ☐

9. Women may not be pregnant, lactating or planning pregnancy during the course of the study. 9. ☐

10. Male or female age 30 years or older at Screening. 10. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 7, 8 and 10 must be **1 = Yes,** and item 9 must be **1 = Yes** if female of child bearing potential

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

6. Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening. 6. ☐

7. Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture. 7. ☐

8. Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia. 8. ☐

9. Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation. 9. ☐

10. Use of investigational drugs or devices within 60 days prior to Baseline (dietary supplements taken outside of a clinical trial are not exclusionary, e.g., coenzyme Q10). 10. ☐

SUBJECT ID | | | | | VISIT NO | | | |

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes) Continued

11. Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator). 11. [ ]

13. Current or active clinically significant neurological disorder (in the opinion of the Investigator). 13. [ ]

14. First degree relative with idiopathic PD (parent, sibling, child). 14. [ ]

15. MoCA score less than or equal to 26. 15. [ ]

To be **ELIGIBLE** for study participation **ALL** answers to items 6-15 must be **0 = No**

To discuss questionable subject eligibility, call the CTCC Project Manager.

PROTOCOL DEVIATION CODE

PPMI

1 3 2 **AV-133 ELIGIBILITY** 1 1

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. ☐ Check box if subject signed consent to participate in the ^{18}F-AV-133-PPMI companion protocol.

B. Date informed consent for participation in ^{18}F-AV-133-PPMI companion protocol was signed: B. | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Women of childbearing potential must be using effective method of birth control 14 days prior to until at least 24 hours after injection of ^{18}F-AV-133. 1. ☐

To be **ELIGIBLE** for study participation item 1 must be 1 = YES if female of childbearing potential

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Current clinically significant cardiovascular disease or clinically important abnormalities on screening ECG (including but not limited to QTc > 450 msec), prior to the first ^{18}F-AV-133 injection. 1. ☐

2. Currently taking medications that are known to cause QT-prolongation. 2. ☐

3. Currently taking tetrabenazine (TBZ) or amphetamine type medications. 3. ☐

4. Received any of the following medications that might interfere with PET imaging: neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine or amphetamine derivative, within 2 weeks of the screening ^{18}F-AV-133 injection. 4. ☐

5. Current clinically significant endocrine or metabolic disease, pulmonary, renal or hepatic impairment, or cancer (excluding localized basal cell carcinoma and in situ prostate cancer) that would interfere with completion of the study. 5. ☐

6. Have had prior intracranial surgery that would be expected to alter imaging. 6. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-6 must be **0 = No**

PPMI

1 3 2

TELEPHONE FOLLOW-UP

1 2

SUBJECT ID | | | | |

VISIT NO | T | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

INSTRUCTIONS: To be used for Interim Telephone call to subject.

1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. | |

1a. | |

1a. If No (0), please indicate the reason:
1 = phone disconnected
2 = multiple messages left on answering machine were not returned
3 = subject moved - unable to locate

5 = other (specify)_____

If new contact information obtained for the subject (e.g., change of phone number or address) document the new contact information in the subject's study record and Confidential Subject Identification Log.

During the telephone contact:

- Review and record concomitant medications
- Review and record adverse events

2. Comments:

_____

_____

_____

1 3 2

AV-133 TELEPHONE FOLLOW-UP

1 3

SUBJECT ID | | | | |

VISIT NO | A | V | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

INSTRUCTIONS: To be used for follow-up Telephone call to subject.

1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. |

1a. |

1a. If No (0), please indicate the reason:
1 = phone disconnected
2 = multiple messages left on answering machine were not returned
3 = subject moved - unable to locate

5 = other (specify)_____

If new contact information obtained for the subject (e.g., change of phone number or address) document the new contact information in the subject's study record and Confidential Subject Identification Log.

During the telephone contact:

- Review and record concomitant medications
- Review and record adverse events

2. Comments:

_____

_____

_____

PPMI

1 3 2

PD FEATURES

1 4

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. Date of first symptom onset per the subject: 1. | | (MM) | | | | | (YYYY)

2a. Date of Parkinson's disease diagnosis: (Leave blank if patient has a diagnosis other than PD.) 2a. | | (MM) | | | (DD) | | | | (YYYY)

2b. 1 = Actual (ACT), 2 = Day Estimated (Day), 3 = Mon/Day Est. (MD), 4 = Month Est. (Mon) 2b. |

3. Were the following symptoms present at the time of diagnosis? (0 = No, 1 = Yes, U = Unknown)

3a. Resting Tremor 3a. |

3b. Rigidity 3b. |

3c. Bradykinesia 3c. |

3d. Postural instability 3d. |

3e. Other, specify: _____ 3e. |

4. Side predominantly affected at onset (1 = Left, 2 = Right, 3 = Symmetric) 4. |

PPMI

1 3 2 **PRODROMAL DIAGNOSTIC QUESTIONNAIRE** 1 5

SUBJECT ID | | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | | | | | | | |
MM DD YYYY

1. Indicate the current most likely clinical diagnosis from one of the categories listed below (choose one): 1. | |

01 = Idiopathic PD
02 = Alzheimer's disease
03 = Chromosome-17 frontotemporal dementia
04 = Corticobasal degeneration
05 = Dementia with Lewy bodies
06 = Dopa-responsive dystonia
07 = Essential tremor
08 = Hemiparkinson/hemiatrophy syndrome
09 = Juvenile autosomal recessive parkinsonism
10 = Motor neuron disease with parkinsonism
11 = Multiple system atrophy
12 = Neuroleptic-induced parkinsonism
13 = Normal pressure hydrocephalus
14 = Progressive supranuclear palsy
15 = Psychogenic illness
16 = Vascular parkinsonism
17 = No PD nor other neurological disorder
18 = Spinocerebellar Ataxia (SCA)
23 = Prodromal non-motor PD (at least one non-motor symptom and no motor symptoms)
24 = Prodromal motor PD (at least one motor symptom to meet eligibility for enrollment in PPMI as PD subject)
97 = Other neurological disorder(s) (specify)_____

2. To what degree are you confident that this subject has motor signs consistent with a parkinsonian syndrome (PS) (any condition in which there is neurodegeneration of dopaminergic cells in the substantia nigra)? 2. |

1 = Motor abnormalities that are signs of PS (90 - 100%)

2 = Motor abnormalities that are likely signs of PS (70 - 89%)

3 = Motor abnormalities that may be signs of PS (50 - 69%)

4 = Non-specific motor abnormalities (25 - 49%)

5 = No evidence of parkinsonian motor signs (0 - 24%)

PPMI

1 3 2

PRIMARY DIAGNOSIS

1 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

2. Most likely primary diagnosis: 2. | |

01 = Idiopathic PD
02 = Alzheimer's disease
03 = Chromosome-17 frontotemporal dementia
04 = Corticobasal degeneration
05 = Dementia with Lewy bodies
06 = Dopa-responsive dystonia
07 = Essential tremor
08 = Hemiparkinson/hemiatrophy syndrome
09 = Juvenile autosomal recessive parkinsonism
10 = Motor neuron disease with parkinsonism
11 = Multiple system atrophy
12 = Neuroleptic-induced parkinsonism
13 = Normal pressure hydrocephalus
14 = Progressive supranuclear palsy
15 = Psychogenic illness
16 = Vascular parkinsonism
17 = No PD nor other neurological disorder
18 = Spinocerebellar Ataxia (SCA)
97 = Other neurological disorder(s) (specify)_____

Examiner | | | | |
STAFF CODE

PPMI

1 3 2 **DIAGNOSTIC FEATURES (PD)** 1 7

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Factors Suggesting a Diagnosis: Questions below are based on the **INVESTIGATOR's** opinion.
Which of the following features are present and therefore might have an impact on the correct diagnosis?
Answer 0 = No or 1 = Yes for each item.

1. Excessive stroke risk factors (e.g., diabetes, hypertension, cardiovascular disease) or past symptoms suggestive of cerebrovascular disease — 1. ☐
2. Unusual or atypical risk factors, exposure, or past history (e.g., drug exposure, acute or chronic toxin exposure, acute infection preceding parkinsonism, repeated head trauma, boxer) — 2. ☐
3. Unusual or atypical presenting features or symptoms — 3. ☐
4. Unusual or atypical course of disease:
   - 4.1 Very rapid progression — 4.1 ☐
   - 4.2 Static or little change — 4.2 ☐
   - 4.3 Hemiparkinsonism longer than 6 years — 4.3 ☐
   - 4.4 Onset before age 30 — 4.4 ☐
   - 4.5 Other, specify: _____ — 4.5 ☐

Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

5. Tremor:
   - 5.1 Resting tremor present and typical for PD — 5.1 ☐
   - 5.2 Resting tremor absent — 5.2 ☐
   - 5.3 Prominent action tremor — 5.3 ☐
   - 5.4 Other, specify: _____ — 5.4 ☐
6. Rigidity:
   - 6.1 Rigidity is present and typical for PD — 6.1 ☐
   - 6.2 Rigidity is absent — 6.2 ☐
   - 6.3 Axial rigidity in excess of distal rigidity — 6.3 ☐
   - 6.4 Marked unilateral or asymmetric rigidity — 6.4 ☐
   - 6.5 Additional type of increased tone (i.e., paratonia, mitgehen, spasticity) — 6.5 ☐
   - 6.6 Other, specify: _____ — 6.6 ☐

Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

7. Akinesia/Bradykinesia:
   - 7.1 Bradykinesia is present and typical for PD — 7.1
   - 7.2 Bradykinesia is absent — 7.2
   - 7.3 Pure Akinesia (without rigidity or tremor) — 7.3
   - 7.4 Bradykinesia does not completely account for difficulty with rapid successive movements (e.g., apraxia, ataxia, pyramidal tract dysfunction) — 7.4
   - 7.5 Other, specify: _____ — 7.5

8. Postural or gait disturbances:
   - 8.1 Postural and gait disturbances are completely typical of PD — 8.1
   - 8.2 Wide-based gait or ataxia — 8.2
   - 8.3 Prominent freezing early in course — 8.3
   - 8.4 Likely to fall if not extra careful — 8.4
   - 8.5 Other, specify: _____ — 8.5

9. Mental Changes:
   - 9.1 Psychiatric — 9.1
   - 9.2 Cognitive — 9.2

10. Other hyperkinesias (not related to levodopa or agonists):
   - 10.1 Dystonia — 10.1
   - 10.2 Chorea — 10.2
   - 10.3 Myoclonus (include stimulus-induced) — 10.3
   - 10.4 Other (e.g., alien limbs): _____ — 10.4

11. Presence of body hemiatrophy — 11.

12. Autonomic disturbances:
   - 12.1 Postural hypotension — 12.1
   - 12.2 Sexual dysfunction — 12.2
   - 12.3 Urinary dysfunction — 12.3
   - 12.4 Bowel dysfunction — 12.4

SUBJECT ID | | | | | VISIT NO | | | |

Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

13. Oculomotor disturbances 13. |

14. Eyelid disturbances (e.g., “apraxia” of lid opening, blepharospasm) 14. |

15. Other neurological abnormalities atypical of parkinsonism (e.g., hyperreflexia, Babinski sign, sensory deficit, amyotrophy, limb apraxia, sleep apnea, dysmetria or other cerebellar dysfunction) 15. |

16. Little or no response to levodopa or a dopamine agonist (Enter N if never treated with dopaminergic medications) 16. |

17. Presence of very rapid speech (tachyphemia) 17. |

18. Presence of dysphagia or other bulbar dysfunction 18. |

19. CT is suggestive of another cause of parkinsonism (Enter N if CT not done) 19. |

20. MRI is suggestive of another cause of parkinsonism (Enter N if MRI not done) 20. |

21. Is there anything unusual or atypical about this subject’s disease (e.g., presentation, symptoms, signs, course, response to therapy, etc.) which could indicate an alternative diagnosis to Parkinson’s disease (i.e., idiopathic parkinsonism with the presence of Lewy bodies in the substantia nigra), no matter how remote? 21. |

Examiner | | | | |
STAFF CODE

PPMI

1 3 2

MEDICAL HISTORY (GENERAL)

1 8

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

NOTE: This form starts with question 1d.

1. Has the subject ever had a significant disorder, disease or surgery of the following systems?

	CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
1d.	Dermatological History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1e.	Ophthalmological History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1f.	ENT History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

	CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
1g.	Pulmonary History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1h.	Cardiovascular History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1i.	Gastrointestinal History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

	CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
1j.	Hepatobiliary History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1k.	Renal History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1l.	Gynecologic/ Urologic History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

1 3 2

MEDICAL HISTORY (GENERAL)

1 8

SUBJECT ID | | | | | VISIT NO | | | |

	CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
1m.	Musculoskeletal History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1n.	Metabolic/ Endocrine History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1o.	Hemato/Lymphatic History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

1 3 2

MEDICAL HISTORY (GENERAL)

1 8

SUBJECT ID | | | | | VISIT NO | | | |

	CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
1p.	Neurologic (other than disease under study) History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1q.	Psychiatric History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1r.	Allergy/ Immunologic Please note drug allergies History? ☐ (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

1s.

CATEGORIES	Enter all **significant** medical history items, including history from birth to present. Specify disorder/diagnosis and onset. **For surgeries, specify reason/diagnosis. Use only one line per description.** If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. **DO NOT ABBREVIATE.**	1 = Active 2 = Resolved	Year of Diagnosis
Other History? ☐ (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

Additional Information

If there are more than 4 medical history items per category, enter in 'Additional information' category below. Indicate which category the condition falls under (e.g., 1a, 1b, etc.). **DO NOT ABBREVIATE.**

Category			
☐☐	A.		
☐☐	B.		
☐☐	C.		
☐☐	D.		
☐☐	E.		
☐☐	F.		
☐☐	G.		

PPMI
FAMILY HISTORY (PD)

1 3 2 | 2 0

SUBJECT ID | VISIT NO

INITIALS | SITE NO | VISIT DATE (MM / DD / YYYY)

		NUMBER of FAMILY MEMBERS	NUMBER with PD or PARKINSONISM
1.	Biological Mother	1.1 1	1.2
2.	Biological Father	2.1 1	2.2
3.	Full Siblings	3.1	3.2
4.	Half Siblings	4.1	4.2
5.	Maternal Grandparents	5.1 2	5.2
6.	Paternal Grandparents	6.1 2	6.2
7.	Maternal Aunts and Uncles	7.1	7.2
8.	Paternal Aunts and Uncles	8.1	8.2
9.	Children	9.1	9.2

PPMI

1 3 2 **GENERAL NEUROLOGICAL EXAM** 2 2

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Cranial Nerves

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

1a. I _____ 1a. ☐

1b. II _____ 1b. ☐

1c. III, IV, VI _____ 1c. ☐

1d. V _____ 1d. ☐

1e. VII _____ 1e. ☐

1f. VIII _____ 1f. ☐

1g. IX, X _____ 1g. ☐

1h. XI _____ 1h. ☐

1i. XII _____ 1i. ☐

Motor System

2. Muscle Strength

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

2a. RIGHT ARM _____ 2a. ☐

2b. LEFT ARM _____ 2b. ☐

2c. RIGHT LEG _____ 2c. ☐

2d. LEFT LEG _____ 2d. ☐

3. Coordination

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

Finger-to-nose

3a. RIGHT HAND _____ 3a.

3b. LEFT HAND _____ 3b.

Heel-to-shin

3c. RIGHT LEG _____ 3c.

3d. LEFT LEG _____ 3d.

Sensory

4. Sensation (pain, light touch, position, vibration)

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

4a. RIGHT ARM _____ 4a.

4b. LEFT ARM _____ 4b.

4c. RIGHT LEG _____ 4c.

4d. LEFT LEG _____ 4d.

Reflexes

5. Muscle Stretch Reflexes

0 = Absent, 1 = Hypoactive, 2 = Normal, 3 = Hyperactive, no clonus, 4 = Hyperactive, clonus, 5 = Not tested, 6 = Unable to test

If response is 5 or 6, describe briefly.

5a. RIGHT ARM _____ 5a.

5b. LEFT ARM _____ 5b.

5c. RIGHT LEG _____ 5c.

5d. LEFT LEG _____ 5d.

6. Plantar Response

0 = Flexor, 1 = Extensor, 2 = Indeterminate, 3 = Not tested, 4 = Unable to test

If response is 3 or 4, describe briefly.

6a. RIGHT _____ 6a.

6b. LEFT _____ 6b.

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1 3 2

GENERAL PHYSICAL EXAM

2 4

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

ORGAN SYSTEM ABNORMALITIES BY EXAMINATION

Use the following Key for items 1-11:
0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

1. Skin _____ 1. ☐

2. Head/Neck/Lymphatic _____ 2. ☐

3. Eyes _____ 3. ☐

4. Ears/Nose/Throat _____ 4. ☐

5. Lungs _____ 5. ☐

SUBJECT ID | | | | | VISIT NO | | | |

ORGAN SYSTEM ABNORMALITIES BY EXAMINATION

Use the following Key for items 1-11:

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

6. Cardiovascular (including peripheral vascular) 6. ☐

_____

_____

_____

7. Abdomen 7. ☐

_____

_____

_____

8. Musculoskeletal 8. ☐

_____

_____

_____

9. Neurological 9. ☐

_____

_____

_____

10. Psychiatric 10. ☐

_____

_____

_____

11. Other (Specify location and describe.) 11. ☐

_____

_____

_____

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1 3 2

VITAL SIGNS

2 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | | | | | | |
MM DD YYYY

1. Weight (in Kilograms) - Baseline and Annual only 1. | | | | . |

2. Height (in Centimeters) - Baseline and Annual only 2. | | | |

3. Temperature (in Celsius) 3. | | . |

4. Arm used to measure blood pressure? (1 = Right arm, 2 = Left arm) 4. |

5. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for
1-3 minutes) 5. | | | / | | |

6. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 6. | | |

9. Standing blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been standing for
1-3 minutes) 9. | | | / | | |

10. Standing heart rate (beats per minute)
(to be taken after subject has been standing for 1-3 minutes) 10. | | |

11. Comments:

_____

_____

_____

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1 3 2

PREGNANCY FORM

2 8

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. If female, was pregancy test performed? (0 = No, 1 = Yes) If No, specify in comments. 1. | |

1a. If the response to question 1 is Yes, is the subject pregnant? (0 = No, 1 = Yes) 1a. | |

1b. Was the urine pregnancy test result confirmed prior to injection for SPECT scan? (0 = No, 1 = Yes, 2 = Not Applicable) If No, specify in comments. 1b. | |

NOTE: If pregnant, consult protocol.

2. Comments:

_____

_____

_____

PPMI

1 3 2 **USE OF PD MEDICATION** 3 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Is the subject on medication for treating the symptoms of Parkinson disease? (0 = No, 1 = Yes) 1. | |

2. If yes, what is the subject taking: (check all that apply)

- ☐ Levodopa
- ☐ Dopamine Agonist
- ☐ Other

NOTE: Complete Questions 3 - 6 for subjects taking levodopa or dopamine agonist as of Month 12 and/or subsequent annual visit(s). Subject will have full MDS-UPDRS (Part I - IV) assessed off medication, followed by repeat Part III motor exam one hour after dosing in clinic (complete MDS-UPDRS Post Dose worksheet).

3. Was the full MDS-UPDRS assessed at this visit prior to dosing in clinic? (0 = No, 1 = Yes) 3. | |

4. Date of most recent PD medication dosing: 4. | | | | | | | | | MM | | DD | | | | | YYYY

5. Time of most recent PD medication dosing prior to full MDS-UPDRS being assessed: (24-hour clock) 5. | | : | |

6. Time that the full MDS-UPDRS was administered prior to dosing in clinic: (24-hour clock) 6. | | : | |

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1 3 2 **MODIFIED SCHWAB & ENGLAND ACTIVITIES OF DAILY LIVING** 3 2

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

100% Completely independent. Able to do all chores without slowness, difficulty or impairment. Essentially normal. Unaware of any difficulty.

90% Completely independent. Able to do all chores with some degree of slowness, difficulty and impairment. Might take twice as long. Beginning to be aware of difficulty.

80% Completely independent in most chores. Takes twice as long. Conscious of difficulty and slowness.

70% Not completely independent. More difficulty with some chores. Three to four times as long in some. Must spend a large part of the day with chores.

60% Some dependency. Can do most chores, but exceedingly slowly and with much effort. Errors; some impossible.

50% More dependent. Help with half, slower, etc. Difficulty with everything.

40% Very dependent. Can assist with all chores but few alone.

30% With effort, now and then does a few chores alone or begins alone. Much help needed.

20% Nothing alone. Can be a slight help with some chores. Severe invalid.

10% Totally dependent, helpless. Complete invalid.

0% Vegetative functions such as swallowing, bladder, and bowel functions are not functioning. Bedridden.

Consensus rating
(Investigator, patient, other sources) 1. | | | |

Examiner | | | | |
STAFF CODE

Fahn S, Elton RL, Members of the UPDRS Development Committee. The Unified Parkinson's Disease Rating Scale. In Fahn S, Marsden CD, Calne DB, Goldstein M, eds. Recent developments in Parkinson's disease, vol 2. Florham Park, NJ: Macmillan Health Care Information, 1987:153-163, 293-304

PPMI

1 3 2

MDS-UPDRS (POST DOSE)

3 4

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

A. Time of PD medication dosing in clinic: (24-hour clock) A. | | | : | | |

B. Time Part III and Hoehn & Yahr administered: B. | | | : | | |

3.1 Speech | |

3.2 Facial expression | |

3.3a Rigidity - Neck | |

3.3b Rigidity - RUE | |

3.3c Rigidity - LUE | |

3.3d Rigidity - RLE | |

3.3e Rigidity - LLE | |

3.4a Finger Tapping Right Hand | |

3.4b Finger Tapping Left Hand | |

3.5a Hand movements - Right Hand | |

3.5b Hand movements - Left Hand | |

3.6a Pronation - Supination Movements - Right Hand | |

3.6b Pronation - Supination Movements - Left Hand | |

3.7a Toe tapping - Right foot | |

3.7b Toe tapping - Left foot | |

3.8a Leg agility - Right leg | |

3.8b Leg agility - Left leg | |

3.9 Arising from chair | |

3.10 Gait | |

3.11 Freezing of gait | |

3.12 Postural stability | |

3.13 Posture | |

3.14 Global spontaneity of movement | |

3.15a Postural tremor - Right hand | |

3.15b Postural tremor - Left hand | |

3.16a Kinetic tremor - Right hand | |

3.16b Kinetic tremor - Left hand | |

3.17a Rest tremor amplitude - RUE | |

3.17b Rest tremor amplitude - LUE | |

3.17c Rest tremor amplitude - RLE | |

3.17d Rest tremor amplitude - LLE | |

3.17e Rest tremor amplitude - Lip/jaw | |

3.18 Constancy of rest | |

3.19 Were dyskinesias present ☐ No ☐ Yes

3.20 Did these movements interfere with ratings ☐ No ☐ Yes

3.21 Hoehn and Yahr Stage | |

Examiner | | | | | STAFF CODE

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1 3 2 **HOPKINS VERBAL LEARNING TEST - REVISED** 3 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Record scores below from the HVLT-R Test Booklet.

1. Hopkins Verbal Learning Test - Revised

1.1	Immediate Recall Trial 1 (# correct)	1. 1
1.2	Immediate Recall Trial 2 (# correct)	1. 2
1.3	Immediate Recall Trial 3 (# correct)	1. 3
1.4	Delayed Recall Trial 4 (# correct after 20 minutes delay)	1. 4
1.5	Delayed recognition - Total # of true - positive responses (“hits”)	1. 5
1.6	Delayed recognition - # of <u>related</u> false - positive errors	1. 6
1.7	Delayed recognition - # of <u>unrelated</u> false - positive errors	1. 7

2. Indicate the HVLT-R test booklet used at this visit (if different than indicated in the protocol, comment below):

- ☐ Form 1
- ☐ Form 2
- ☐ Form 3
- ☐ Form 4
- ☐ Form 5
- ☐ Form 6

Comment:_____

_____

_____

PPMI

1 3 2

SEMANTIC FLUENCY

3 8

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. Record the number of animals named in one minute (60 seconds): 1. | |

2. Record the number of vegetables named in one minute (60 seconds): 2. | |

3. Record the number of fruits named in one minute (60 seconds): 3. | |

PPMI

1 3 2

LETTER - NUMBER SEQUENCING (PD)

4 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Instructions: All responses should be recorded verbatim in the "Subject Response" section below. Score 1 for each correct response and 0 for each incorrect response. Discontinue Rule: After scores of 0 for all 3 trials of an item.

Item	Trial (Correct Response)	Subject Response	Score (0 or 1)
1a.	L - 2 (2 - L)		1a. ☐
1b.	6 - P (6 - P)		1b. ☐
1c.	B - 5 (5 - B)		1c. ☐
2a.	F - 7 - L (7 - F - L)		2a. ☐
2b.	R - 4 - D (4 - D - R)		2b. ☐
2c.	H - 1 - 8 (1 - 8 - H)		2c. ☐
3a.	T - 9 - A - 3 (3 - 9 - A - T)		3a. ☐
3b.	V - 1 - J - 5 (1 - 5 - J - V)		3b. ☐
3c.	7 - N - 4 - L (4 - 7 - L - N)		3c. ☐
4a.	8 - D - 6 - G - 1 (1 - 6 - 8 - D - G)		4a. ☐
4b.	K - 2 - C - 7 - S (2 - 7 - C - K - S)		4b. ☐
4c.	5 - P - 3 - Y - 9 (3 - 5 - 9 - P - Y)		4c. ☐

LETTER - NUMBER SEQUENCING (PD)

SUBJECT ID | | | | | VISIT NO | | | |

Instructions: All responses should be recorded verbatim in the "Subject Response" section below. Score 1 for each correct response and 0 for each incorrect response. Discontinue Rule: After scores of 0 for all 3 trials of an item.

Item	Trial (Correct Response)	Subject Response	Score (0 or 1)
5a.	M - 4 - E - 7 - Q - 2 (2 - 4 - 7 - E - M - Q)		5a.
5b.	W - 8 - H - 5 - F - 3 (3 - 5 - 8 - F - H - W)		5b.
5c.	6 - G - 9 - A - 2 - S (2 - 6 - 9 - A - G - S)		5c.
6a.	R - 3 - B - 4 - Z - 1 - C (1 - 3 -4 - B - C - R - Z)		6a.
6b.	5 - T - 9 - J - 2 - X - 7 (2 - 5 - 7 - 9 - J - T - X)		6b.
6c.	E - 1 - H - 8 - R - 4 - D (1 - 4 - 8 - D - E - H - R)		6c.
7a.	5 - H - 9 - S - 2 - N - 6 - A (2 - 5 - 6 - 9 - A - H - N - S)		7a.
7b.	D - 1 - R - 9 - B - 4 - K - 3 (1 - 3 - 4 - 9 - B - D - K - R)		7b.
7c.	7 - M - 2 - T - 6 - F - 1 - Z (1 - 2 - 6 - 7 - F- M - T - Z)		7c.

PPMI

1 3 2

SYMBOL DIGIT MODALITIES TEST

4 2

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | | | | | | | |

MM DD YYYY

1. Total correct (Response should be 0-110) 1. | | | |

2. Indicate the form used at this visit (if different than indicated in the protocol, comment below):

- ☐ Form 1
- ☐ Form 2

Comment:_____

_____

_____

PPMI

1 3 2 **EPWORTH SLEEPINESS SCALE** 4 4

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver A. | |

How likely are you to doze off or fall asleep in situations described below, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

1. Sitting and reading 1. | |
2. Watching TV 2. | |
3. Sitting, inactive in a public place (e.g., a theatre or a meeting) 3. | |
4. As a passenger in a car for an hour without a break 4. | |
5. Lying down to rest in the afternoon when circumstances permit 5. | |
6. Sitting and talking to someone 6. | |
7. Sitting quietly after a lunch without alcohol 7. | |
8. In a car, while stopped for a few minutes in the traffic 8. | |

PPMI
REM SLEEP DISORDER QUESTIONNAIRE

1 3 2 | 4 6

SUBJECT ID | VISIT NO

INITIALS | SITE NO | VISIT DATE (MM / DD / YYYY)

A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver — A.

1. I sometimes have very vivid dreams. (0 = No, 1 = Yes) — 1.

2. My dreams frequently have an aggressive or action-packed content. (0 = No, 1 = Yes) — 2.

3. The dream contents mostly match my nocturnal behaviour. (0 = No, 1 = Yes) — 3.

4. I know that my arms or legs move when I sleep. (0 = No, 1 = Yes) — 4.

5. It thereby happened that I (almost) hurt my bed partner or myself. (0 = No, 1 = Yes) — 5.

6. I have or had the following phenomena during my dreams:

   6.1 speaking, shouting, swearing, laughing loudly (0 = No, 1 = Yes) — 6.1

   6.2 sudden limb movements, “fights” (0 = No, 1 = Yes) — 6.2

   6.3 gestures, complex movements, that are useless during sleep, e.g., to wave, to salute, to frighten mosquitoes, falls off the bed (0 = No, 1 = Yes) — 6.3

   6.4 things that fell down around the bed, e.g., bedside lamp, book, glasses (0 = No, 1 = Yes) — 6.4

7. It happens that my movements awake me. (0 = No, 1 = Yes) — 7.

8. After awakening I mostly remember the content of my dreams well. (0 = No, 1 = Yes) — 8.

9. My sleep is frequently disturbed. (0 = No, 1 = Yes) — 9.

PPMI
REM SLEEP DISORDER QUESTIONNAIRE

SUBJECT ID | | | | | VISIT NO | | | |

10. I have/had a disease of the nervous system: (0 = No, 1 = Yes)

10a.	stroke	10a. ☐
10b.	head trauma	10b. ☐
10c.	parkinsonism	10c. ☐
10d.	RLS	10d. ☐
10e.	narcolepsy	10e. ☐
10f.	depression	10f. ☐
10g.	epilepsy	10g. ☐
10h.	inflammatory disease of the brain	10h. ☐
10i.	other, specify: _____	10i. ☐

PPMI

1 3 2

GERIATRIC DEPRESSION SCALE (Short Version)

4 8

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Choose the best answer for how you have felt over the **past week**. (0 = No, 1 = Yes)

1.	Are you basically satisfied with your life?	1.
2.	Have you dropped many of your activities and interests?	2.
3.	Do you feel that your life is empty?	3.
4.	Do you often get bored?	4.
5.	Are you in good spirits most of the time?	5.
6.	Are you afraid that something bad is going to happen to you?	6.
7.	Do you feel happy most of the time?	7.
8.	Do you often feel helpless?	8.
9.	Do you prefer to stay at home, rather than going out and doing new things?	9.
10.	Do you feel you have more problems with memory than most?	10.
11.	Do you think it is wonderful to be alive now?	11.
12.	Do you feel pretty worthless the way you are now?	12.
13.	Do you feel full of energy?	13.
14.	Do you feel that your situation is hopeless?	14.
15.	Do you think that most people are better off than you are?	15.

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease (QUIP-Current-Short)

Reported : _____ Patient _____ Informant* _____ Patient and Informant

Patient name: _____

Date: _____

*If information reported by an informant, answer questions based on your understanding of the patient.

Answer ALL QUESTIONS based on CURRENT BEHAVIORS LASTING AT LEAST 4 WEEKS

A. GAMBLING

1. Do you or others think you have an issue with too much gambling behaviors (such as casinos, internet gambling, lotteries, scratch tickets, betting, or slot or poker machines)? __Yes __No

2. Do you have difficulty controlling your gambling behaviors (such as increasing them over time, or having trouble cutting down or stopping them)? __Yes __No

B. SEX

1. Do you or others think you have an issue with too much sex behaviors (such as making sexual demands on others, promiscuity, prostitution, change in sexual orientation, masturbation, internet or telephone sexual activities, or pornography)? __Yes __No

2. Do you think too much about sex behaviors (such as having trouble keeping thoughts out of your mind or feeling guilty)? __Yes __No

C. BUYING

1. Do you or others think you have an issue with too much buying behaviors (such as too much of the same thing or things that you don't need or use)? __Yes __No

2. Do you engage in activities specifically to continue the buying behaviors (such as hiding what you're doing, lying, hoarding things, borrowing from others, accumulating debt, stealing, or being involved in illegal acts)? __Yes __No

D. EATING

1. Do you or others think you have an issue with too much eating behaviors (such as eating larger amounts or different types of food than in the past, more rapidly than normal, until feeling uncomfortably full, or when not hungry)? __Yes __No

2. Do you have urges or desires for eating behaviors that you feel are excessive or cause you distress (including becoming restless or irritable when unable to participate in the behavior)? __Yes __No

SUBJECT ID | | | | | VISIT NO | | | |

Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease (QUIP-Current-Short)

E. OTHER BEHAVIORS

Do you or others think that you spend too much time….

1. On specific tasks, hobbies or other organized activities (such as writing, painting, gardening, repairing or dismantling things, collecting, computer use, working on projects, etc.)? __Yes __No

2. Repeating certain simple motor activities (such as cleaning, tidying, handling, examining, sorting, ordering, or arranging objects, etc.)? __Yes __No

3. Walking or driving with no intended goal or specific purpose? __Yes __No

F. MEDICATION USE

1. Do you or others (including your physicians) think that you consistently take too much of your Parkinson's medications? __Yes __No __Not Applicable

2. Do you have difficulty controlling your use of Parkinson's medications (such as experiencing a strong desire-for more medication, or having worse mood or feeling unmotivated at a lower dosage)?
__Yes __No __Not Applicable

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver A. | |

SCOPA-AUT

By means of this questionnaire, we would like to find out to what extent in the past month you have had problems with various bodily functions, such as difficulty passing urine, or excessive sweating. Answer the questions by placing a cross in the box which best reflects your situation. If you wish to change an answer, fill in the 'wrong' box and place a cross in the correct one. If you have used medication in the past month in relation to one or more of the problems mentioned, then the question refers to how you were while taking this medication. You can note the use of medication on the last page.

1. In the past month have you had difficulty swallowing or have you choked?

never	sometimes	regularly	often
☐	☐	☐	☐

2. In the past month, has saliva dribbled out of your mouth?

never	sometimes	regularly	often
☐	☐	☐	☐

3. In the past month, has food ever become stuck in your throat?

never	sometimes	regularly	often
☐	☐	☐	☐

4. In the past month, did you ever have the feeling during a meal that you were full very quickly?

never	sometimes	regularly	often
☐	☐	☐	☐

5. *Constipation is a blockage of the bowel, a condition in which someone has a bowel movement twice a week or less.*
In the past month, have you had problems with constipation?

never	sometimes	regularly	often
☐	☐	☐	☐

6. In the past month, did you have to strain hard to pass stools?

never	sometimes	regularly	often
☐	☐	☐	☐

SUBJECT ID | | | | | VISIT NO | | | |

7. In the past month, have you had involuntary loss of stools?

☐ never ☐ sometimes ☐ regularly ☐ often

Questions 8 to 13 deal with problems with passing urine. If you use a catheter you can indicate this by placing a cross in the box *"use catheter"*.

8. In the past month, have you had difficulty retaining urine?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

9. In the past month, have you had involuntary loss of urine?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

10. In the past month, have you had the feeling that after passing urine your bladder was not completely empty?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

11. In the past month, has the stream of urine been weak?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

12. In the past month, have you had to pass urine again within 2 hours of the previous time?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

13. In the past month, have you had to pass urine at night?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *use catheter*

SUBJECT ID | | | | | VISIT NO | | | |

14. In the past month, when standing up have you had the feeling of either becoming light-headed, or no longer being able to see properly, or no longer being able to think clearly?

☐ never ☐ sometimes ☐ regularly ☐ often

15. In the past month, did you become light-headed after standing for some time?

☐ never ☐ sometimes ☐ regularly ☐ often

16. Have you fainted in the past 6 months?

☐ never ☐ sometimes ☐ regularly ☐ often

17. In the past month, have you ever perspired excessively during the day?

☐ never ☐ sometimes ☐ regularly ☐ often

18. In the past month, have you ever perspired excessively during the night?

☐ never ☐ sometimes ☐ regularly ☐ often

19. In the past month, have your eyes ever been over-sensitive to bright light?

☐ never ☐ sometimes ☐ regularly ☐ often

20. In the past month, how often have you had trouble tolerating cold?

☐ never ☐ sometimes ☐ regularly ☐ often

21. In the past month, how often have you had trouble tolerating heat?

☐ never ☐ sometimes ☐ regularly ☐ often

SUBJECT ID | | | | | VISIT NO | | | |

The following questions are about sexuality. Although we are aware that sexuality is a highly intimate subject, we would still like you to answer these questions. For the questions on sexual activity, consider every form of sexual contact with a partner or masturbation (self-gratification). An extra response option has been added to these questions. Here you can indicate that the situation described has not been applicable to you in the past month, for example because you have not been sexually active. Questions 22 and 23 are intended specifically for men, 24 and 25 for women.

The following 3 questions are only for men

22. In the past month, have you been impotent (unable to have or maintain an erection)?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *not applicable*

23. In the past month, how often have you been unable to ejaculate?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *not applicable*

23a. In the past month, have you taken medication for an erection disorder? (If so, which medication?)

☐ no ☐ yes: _____

Proceed with question 26

The following 2 questions are only for women

24. In the past month, was your vagina too dry during sexual activity?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *not applicable*

25. In the past month, have you had difficulty reaching an orgasm?

☐ never ☐ sometimes ☐ regularly ☐ often ☐ *not applicable*

SUBJECT ID | | | | | VISIT NO | | | |

The following questions are for everyone

26. In the past month, have you used medication for:

a. constipation? ☐ no ☐ yes: _____

b. urinary problems? ☐ no ☐ yes: _____

c. blood pressure? ☐ no ☐ yes: _____

d. other symptoms *(not symptoms related to Parkinson's disease)* ☐ no ☐ yes: _____

_____

Visser M, Marinus J, Stiggelbout AM, van Hilten JJ. Assessment of autonomic dysfunction in Parkinson's disease: The SCOPA-AUT. Mov Disord. 2004;19:1306-12.

For further information, please contact M.Visser, Leiden University Medical Center, Department of Neurology (K5Q), P.O. Box 9600, NL-2300 RC Leiden (email: m.visser@lumc.nl).

PPMI

1 3 2 **COGNITIVE CATEGORIZATION** 5 3

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. Indicate the source of information: A. | |
1 = Subject, 2 = Caregiver, 3 = Subject and Caregiver

Determining Report of Cognitive Decline

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a decline in cognition compared with pre-morbid abilities (i.e., pre-PD). The following cognitive abilities should be considered:

Attention: Ability to sustain and direct attention, lapses

Memory: Registration, recall of recent events or important dates, new learning ability, misplacement of items, forgetting items

Orientation: Forgetting appointments, estimating time, spatial or geographical orientation

Executive abilities: Reasoning ability, making decisions, following instructions, difficulty with calculations

Praxis: Constructional or mechanical cognitive ability, such as use of tools and appliances

Language: Word finding problems, problems with naming or comprehension

1. Has the subject experienced cognitive decline? (0 = No, 1 = Yes) 1. | |

Determining Functional Impairment

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a significant decline in functional abilities (from a cognitive standpoint) to the extent of demonstrating impairment in performing instrumental activities of daily living, examples of which include: driving, managing finances, managing medications, shopping, food preparation, participation in hobbies and employment.

2. Does the subject have clinically significant functional impairment as a result of cognitive impairment? (0 = No, 1 = Yes) 2. | |

Determining Cognitive Diagnosis

Based on your impression of the subject's current cognitive function, which may include performance on neuropsychological testing, as well as your knowledge of his/her pre-morbid cognitive function and the degree to which cognitive deficits impact his/her ability to carry out daily activities, please rate the subject's current cognitive status. The determination of dementia implies (1) cognitive function that is impaired in more than one cognitive domain, (2) decline from pre-morbid function, and (3) significant impact of cognitive impairment on daily function. The determination of MCI is based on (1) impairment in at least one cognitive domain, (2) decline from pre-morbid function, and (3) lack of significant impact of cognitive impairment on daily function.

3. Based on your clinical impression, which of the following categories best describes the subject's cognitive state: 3. ☐

1 = Normal Cognition (PD-NC)
2 = Mild Cognitive Impairment (PD-MCI)
3 = Dementia (PDD)

4. What is your level of confidence of this cognitive diagnosis? 4. ☐

1 = 90 - 100%
2 = 50 - 89%
3 = 10 - 49%
4 = 0 - 9%

5. Did you review any neuropsychological tests (including MoCA scores) in making this determination? (0 = No, 1 = Yes) 5. ☐

PPMI

1 3 2 **RETROSPECTIVE COGNITIVE CATEGORIZATION** 5 3

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. Indicate the source of information: A. | |
1 = Subject, 2 = Caregiver, 3 = Subject and Caregiver

Determining Report of Cognitive Decline

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a decline in cognition compared with pre-morbid abilities (i.e., pre-PD). The following cognitive abilities should be considered:

Attention: Ability to sustain and direct attention, lapses

Memory: Registration, recall of recent events or important dates, new learning ability, misplacement of items, forgetting items

Orientation: Forgetting appointments, estimating time, spatial or geographical orientation

Executive abilities: Reasoning ability, making decisions, following instructions, difficulty with calculations

Praxis: Constructional or mechanical cognitive ability, such as use of tools and appliances

Language: Word finding problems, problems with naming or comprehension

1. Has the subject experienced cognitive decline? (0 = No, 1 = Yes) 1. | |

Determining Functional Impairment

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a significant decline in functional abilities (from a cognitive standpoint) to the extent of demonstrating impairment in performing instrumental activities of daily living, examples of which include: driving, managing finances, managing medications, shopping, food preparation, participation in hobbies and employment.

2. Does the subject have clinically significant functional impairment as a result of cognitive impairment? (0 = No, 1 = Yes) 2. | |

Determining Cognitive Diagnosis

Based on your impression of the subject's current cognitive function, which may include performance on neuropsychological testing, as well as your knowledge of his/her pre-morbid cognitive function and the degree to which cognitive deficits impact his/her ability to carry out daily activities, please rate the subject's current cognitive status. The determination of dementia implies (1) cognitive function that is impaired in more than one cognitive domain, (2) decline from pre-morbid function, and (3) significant impact of cognitive impairment on daily function. The determination of MCI is based on (1) impairment in at least one cognitive domain, (2) decline from pre-morbid function, and (3) lack of significant impact of cognitive impairment on daily function.

3. Based on your clinical impression, which of the following categories best describes the subject's cognitive state: 3. ☐

1 = Normal Cognition (PD-NC)
2 = Mild Cognitive Impairment (PD-MCI)
3 = Dementia (PDD)

4. What is your level of confidence of this cognitive diagnosis? 4. ☐

1 = 90 - 100%
2 = 50 - 89%
3 = 10 - 49%
4 = 0 - 9%

5. Did you review any neuropsychological tests (including MoCA scores) in making this determination? (0 = No, 1 = Yes) 5. ☐

PPMI

1 3 2 **UNIVERSITY OF PENNSYLVANIA SMELL ID TEST** 5 4

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | SITE NO | | | VISIT DATE | | | MM | | DD | | | | YYYY

Record score from each booklet.

1. Score from booklet #1: 1. | |

2. Score from booklet #2: 2. | |

3. Score from booklet #3: 3. | |

4. Score from booklet #4: 4. | |

5. Comments:

_____

_____

_____

PPMI

DNA SAMPLE

1 3 2 | 5 6

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Blood sample for DNA: (0 = Not Collected, 1 = Collected) 1. |

1a. Date blood sample for DNA collected: 1a. | | MM | | DD | | | | | YYYY

2. Volume of blood collected: (milliliters) 2. | |

3. Date DNA sample shipped: 3. | | MM | | DD | | | | | YYYY

PPMI

1 3 2

LABORATORY PROCEDURES

5 8

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Date of last intake of food: 1. | | MM | | DD | | | | YYYY

1a. Time of last intake of food: (24-hour clock) 1a. | | : | |

1b. Fasting status:
(1 = Fasted (minimum of 8 hours), 2 = Low Fat Diet, 3 = Not Fasted, No Low Fat Diet) 1b. |

2. Is subject on medication for PD? (0 = No, 1 = Yes) 2. |

2a. Date of most recent PD medication dosing: 2a. | | MM | | DD | | | | YYYY

2b. Time of most recent PD medication dosing: (24-hour clock) 2b. | | : | |

Urine Sample Collection

3. Urine for storage and analysis: (0 = Not collected, 1 = Collected) 3. |

3a. Date of urine sample collection: 3a. | | MM | | DD | | | | YYYY

3b. Time of urine sample collection: (24-hour clock) 3b. | | : | |

3c. Time of centrifugation: (24-hour clock) 3c. | | : | |

3d. Rate of centrifugation: (xg) 3d. | | | |

3e. Duration of centrifugation: (minutes) 3e. | |

3f. Indicate temperature at which tube was spun: (Celsius) 3f. | |

3g. Time urine sample placed in freezer: (24-hour clock) 3g. | | : | |

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

Blood Sample Collection

4. Date blood samples collected: 4. [ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

(RNA – PAXgene RED TOP)

5. Blood for PAXgene/RNA: (0 = Not collected, 1 = Collected) 5. [ ]

5a. Time of PAXgene/RNA sample collection: (24-hours at room temperature) 5a. [ ][ ] : [ ][ ]

5b. Date PAXgene/RNA samples placed in freezer: 5b. [ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

5c. Time PAXgene/RNA samples placed in freezer: 5c. [ ][ ] : [ ][ ]

5d. Storage temperature: (Celsius) 5d. - [ ][ ]

(PLASMA – EDTA PURPLE TOP)

6. Blood for plasma: (0 = Not collected, 1 = Collected) 6. [ ]

6a. Time of plasma sample collection: (24-hour clock) 6a. [ ][ ] : [ ][ ]

6b. Time of centrifugation: (24-hour clock) 6b. [ ][ ] : [ ][ ]

6c. Rate of centrifugation: (xg) 6c. [ ][ ][ ][ ]

6d. Duration of centrifugation: (minutes) 6d. [ ][ ]

6e. Indicate temperature at which tube was spun: (Celsius) 6e. [ ][ ]

6f. Total volume aliquotted after spinning: (milliliters) 6f. [ ] . [ ]

6g. Total number of aliquot tubes: 6g. [ ]

6h. Time plasma samples placed in freezer: (24-hour clock) 6h. [ ][ ] : [ ][ ]

6i. Storage temperature: (Celsius) 6i. - [ ][ ]

6j. Buffy coat: (0 = Not collected, 1 = Collected) 6j. [ ]

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

(SERUM – RED TOP)

7. Blood for serum: (0 = Not collected, 1 = Collected) 7. [ ]

7a. Time of serum sample collection: (24-hour clock) 7a. [ ][ ] : [ ][ ]

7b. Time of centrifugation: (24-hour clock) 7b. [ ][ ] : [ ][ ]

7c. Rate of centrifugation: (xg) 7c. [ ][ ][ ][ ]

7d. Duration of centrifugation: (minutes) 7d. [ ][ ]

7e. Indicate temperature at which tube was spun: (Celsius) 7e. [ ][ ]

7f. Total volume aliquotted after spinning: (milliliters) 7f. [ ] . [ ]

7g. Total number of aliquot tubes: 7g. [ ]

7h. Time serum samples placed in freezer: (24-hour clock) 7h. [ ][ ] : [ ][ ]

7i. Storage temperature: (Celsius) 7i. [-][ ][ ]

Comments:

_____

_____

_____

PPMI

1 3 2

CLINICAL LABS

5 9

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Blood for clinical labs: (0 = Not collected, 1 = Collected) 1. | |
   If Not Collected (0), provide reason in Comments.

   1a. Date shipped to central lab: 1a. | | MM | | DD | | | | | YYYY

Comments:

_____

_____

_____

PPMI

1 3 2 **MAGNETIC RESONANCE IMAGING** 6 0

SUBJECT ID ____ VISIT NO ____

INITIALS ____ SITE NO ____ VISIT DATE __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

1. MRI scan: (0 = Not Completed, 1 = Completed) 1. ____
If Not Completed (0), provide reason in Comments.

1a. Date MRI scan completed: 1a. __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

1b. Did MRI scan include DTI sequences? (0 = No, 1 = Yes) 1b. ____

1c. Did MRI scan include resting state sequences? (0 = No, 1 = Yes) 1c. ____

1c1. If 1c is 1 = Yes, were MRI resting state sequences completed on a different day than the Use of PD Medication form? (0 = No, 1 = Yes) 1c1. ____

1c2. If 1c1 is 1 = Yes, is the subject on medication for treating the symptoms of Parkinson disease? (0 = No, 1 = Yes) 1c2. ____

1c3. If 1c2 is 1 = Yes, what is the subject taking: (check all that apply)

- ☐ Levodopa
- ☐ Dopamine Agonist
- ☐ Other

1c4. Date of last dose prior to scan: 1c4. __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

1c5. Time of last dose prior to scan: (24-hour clock) 1c5. __ __ : __ __

2. MRI data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes) 2. ____

3. MRI scan results (based on radiologist interpretation) are: (Baseline Only) 3. ____
1 = Normal
2 = Abnormal, not clinically significant
3 = Abnormal, clinically significant (specify in Comments)

Comments:

_____

_____

NOTE: DTI sequences at Baseline and annual visits performed at select sites only.

PPMI

1 3 2 **DaTSCAN IMAGING** 6 2

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. SPECT imaging scan: (0 = Not Completed, 1 = Completed) 1. | |
If Not Completed (0), provide reason in Comments.

1a. Date SPECT scan was completed: 1a. | | MM | | DD | | | | | YYYY

1b. Location where SPECT scan was completed? (1 = Site, 2 = IND) 1b. | |

1c. Injection: (1 = DaTSCAN, 2 = Beta-CIT) 1c. | |

2. SPECT imaging data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes) 2. | |

3. SPECT Visual Interpretation Report indicates the scan is (At screening for all subjects and additionally at V06 for SWEDD subjects): 3. | |
1 = Consistent with evidence of dopamine transporter deficit
2 = Not consistent with evidence of dopamine transporter deficit

Note: Women of childbearing potential must have a negative urine pregnancy test result prior to injection.

Comments:

_____

_____

_____

PPMI

1 3 2 **DaTSCAN IMAGING (PRODROMAL)** 6 3

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. SPECT imaging scan: (0 = Not Completed, 1 = Completed) 1. |
If Not Completed (0), provide reason in Comments.

1a. Date SPECT scan was completed: 1a. | | (MM) | | (DD) | | | | | (YYYY)

1b. Location where SPECT scan was completed? (1 = Site, 2 = IND) 1b. |

1c. Injection: (1 = DaTSCAN, 2 = Beta-CIT) 1c. |

2. SPECT imaging data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes) 2. |

3. SPECT Visual Interpretation Report indicates the scan is (Screening only): 3. |
1 = Eligible
2 = Not eligible

Note: Women of childbearing potential must have a negative urine pregnancy test result prior to injection.

Comments:

_____

_____

_____

PPMI

1 3 2 **AV-133 IMAGING** 6 3

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

VITAL SIGNS MEASURED APROXIMATELY 5 MINUTES PRIOR TO INJECTION

A. Was a study physician present to evaluate the subject prior to injection? (0 = No, 1 = Yes) A. [ ]
If Yes, physician to sign and date below:

X _____

1. Time vital signs measured prior to injection: (24-hour clock) 1. [ ][ ] : [ ][ ]

2. Supine blood pressure: systolic/diastolic (mmHg) 2. [ ][ ][ ] / [ ][ ][ ]
(to be taken after subject has been supine for 1-3 minutes)

3. Supine heart rate (beats per minute) 3. [ ][ ][ ]
(to be taken after subject has been supine for 1-3 minutes)

4. If female of childbearing potential, was serum pregnancy test performed (screening Only)? (0 = No, 1 = Yes) 4. [ ]

4a. Indicate the result of the serum pregnancy test: (0 = Negative, 1 = Positive) 4a. [ ]

4b. Was the result of the serum pregnancy test confirmed prior to the first ^{18}F-AV-133 injection? (0 = No, 1 = Yes) 4b. [ ]

5. If female of childbearing potential, was urine pregnancy test performed? (0 = No, 1 = Yes) 5. [ ]

5a. Indicate the result of the urine pregnancy test: (0 = Negative, 1 = Positive) 5a. [ ]

5b. Was the result of the urine pregnancy test confirmed prior to ^{18}F-AV-133 injection? (0 = No, 1 = Yes) 5b. [ ]

Note: Women of childbearing potential must have a negative urine and serum pregnancy test result **prior to** the screening imaging scan and must have a negative urine pregnancy test result **prior to** injection of a follow up imaging scan.

6. Time of ^{18}F-AV-133 injection: (24-hour clock) 6. [ ][ ] : [ ][ ]

VITAL SIGNS MEASURED APPROXIMATELY 15 MINUTES POST-INJECTION

7. Time vital signs measured after ^{18}F-AV-133 injection: (24-hour clock) 7. | | : | |

8. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for 1-3 minutes) 8. | | | / | | |

9. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 9. | | |

10. AV-133 PET imaging scan: (0 = Not Completed, 1 = Completed) 10. |

10a. Date AV-133 PET imaging scan was completed: 10a. | | (MM) | | (DD) | | | | | (YYYY)

10b. Was a study physician (or designee) present to evaluate the subject prior to discharge? (0 = No, 1 = Yes) 11. |
If Yes, physician (or designee) to sign and date below:

X _____

11. AV-133 imaging data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes) 11. |

12. VMAT-2 PET Visual Interpretation Report indicates the scan is (Screening only): 12. |
1 = Consistent with vesicular monoamine transporter (VMAT-2) deficit
2 = Not consistent with vesicular monoamine transporter (VMAT-2) deficit

Comments:

_____

_____

_____

PPMI

1 3 2 **LUMBAR PUNCTURE** 6 4

SUBJECT ID ____ VISIT NO ____

INITIALS ____ SITE NO ____ VISIT DATE __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

A. Date of last intake of food: A. __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

B. Time of last intake of food: (24-hour clock) B. __ __ : __ __

Ba. Fasting status:
(1 = Fasted (minimum of 8 hours), 2 = Low Fat Diet, 3 = Not Fasted, No Low Fat Diet) Ba. __

C. Is subject on medication for PD? (0 = No, 1 = Yes) C. __

Ca. Date of most recent PD medication dosing: Ca. __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

Cb. Time of most recent PD medication dosing (24-hour clock) Cb. __ __ : __ __

1. Lumbar puncture for collection of CSF: 1. __
(0 = Not Done, 1 = Collected, 2 = Partial Collection, 3 = Attempted, no collection)
If response is 0, 2 or 3, specify in comments.

1a. If lumbar puncture not done, please indicate reason why not completed: 1a. __
1 = Subject refused/ subject not feeling well enough to attempt
2 = site issues (e.g., scheduling difficulties on site end)
3 = History of difficulty obtaining LP/subject not able to tolerate procedure in the past; adverse events associated with prior lumbar punctures
4 = Due to spinal issues (e.g., recent back surgery, spinal stenosis, etc.)
5 = Medical contraindications to lumbar puncture (e.g., lab results, altered mentation, focal neurologic signs, papilledema, seizures, tumor)
6 = Subject on medication (e.g., anticoagulants) that precludes subject from completing lumbar puncture
7 = Hyposmic subject who received permission to forego lumbar puncture
8 = Other, specify in comments

2. Date CSF collected: 2. __ __ (MM) __ __ (DD) __ __ __ __ (YYYY)

3. Indicate needle used to collect CSF: 3. __
1 = 20g Quincke (sharp bevelled) needle
2 = 22g Quincke (sharp bevelled) needle
3 = 25g Quincke (sharp bevelled) needle
4 = 22g Sprotte (atraumatic) needle
5 = 24g Sprotte (atraumatic) needle (preferred)
6 = 18g
7 = Other, specify in comments

4. Indicate method of collecting the CSF: 4. |_|
   1 = Gravity
   2 = Syringe suction

5. Lumbar puncture performed at the: 5. |_|
   0 = L2-L3 Interspace
   1 = L3-L4 Interspace
   2 = L4-L5 Interspace
   3 = Unknown

6. Subject position when lumbar puncture performed: 6. |_|
   1 = Sitting, leaned over (preferred)
   2 = Lying, curled up on side
   3 = Unknown
   4 = Other, specify in comments

7. Time CSF collection completed: (24-hour clock) 7. |_|_| : |_|_|

8. Volume of CSF collected prior spinning: (milliliters) 8. |_|_|

9. Time CSF was centrifuged: (24-hour clock) 9. |_|_| : |_|_|
   (Within 15 minutes from sample collection)

10. Rate of centrifugation for the CSF sample: (xg) 10. |_|_|_|_|

11. Temperature at which CSF tube was spun: (Celsius) 11. |_|_|

12. Time CSF sample aliquotted: (24-hour clock) 12. |_|_| : |_|_|

13. Total volume of CSF aliquotted after spinning: (milliliters) 13. |_|_|

14. Total number of aliquot tubes: 14. |_|_|

15. Was part of sample discarded due to a bloody tap? (0 = No, 1 = Yes) 15. |_|

16. Time samples were either placed in freezer or placed on dry ice: 16. |_|_| : |_|_|
    (24-hour clock)

    16a. Storage temperature if placed in freezer: (Celsius) 16a. |-|_|_|

17. Was part of the sample sent to local lab for analyses? (0 = No, 1 = Yes) 17. |_|
    If No, specify in Comments.

18. What is the white blood cell count? 18. | | | | |
18b. Indicate units:

☐ Per cubic millimeter ☐ Per microliter ☐ Per liter ☐ Other_____

19. What is the red blood cell count? 19. | | | | |
19b. Indicate units:

☐ Per cubic millimeter ☐ Per microliter ☐ Per liter ☐ Other_____

20. What is the total protein? 20. | | | . | |

20a. Indicate units: ☐ mg/dL ☐ g/dL ☐ g/L

21. What is the total glucose? 21. | | | . | |

21a. Indicate units: ☐ mg/dL ☐ mmol/L

22. Was a fluoroscopy performed? (0 = No, 1 = Yes) 22. |

22a. Date of fluoroscopy: 22a. | | MM | | DD | | | | | YYYY

23. Was a lumbar spine film performed? (0 = No, 1 = Yes) 23. |

23a. Date of spine film: 23a. | | MM | | DD | | | | | YYYY

Comments:

_____

_____

_____

PPMI

1 3 2 **SIGNATURE FORM** 6 6

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

NOTE: a signature form is required for each expected study visit and telephone contact whether or not the visit or call was actually performed.

1.1 Visit Completion Status: (Include comment for any answer other than 1 or 7 under question 3, Comments.) 1.1 [ ]
1 = Within visit window and conducted by investigator (or coordinator if telephone contact).
2 = Within visit window and not conducted by investigator.
3 = Not done (If visit not done enter the target visit date in the header).
4 = Out of visit window and conducted by investigator (or coordinator if telephone contact).
5 = Out of visit window and not conducted by investigator.
6 = Unscheduled Visit
7 = Other (specify)_____

1.2 Indicate why the subject missed the visit. 1.2 [ ][ ]
1 = Scheduling issue with the subject.
2 = Scheduling issue with the staff.
3 = Family/social issues with the subject.
4 = Subject did not return phone calls to schedule study visit.
5 = Travel Distance
6 = Medical Problems
7 = Military Duty
8 = Financial Issues
9 = Lost to Follow up (complete Conclusion of Study Participation form).
10 = Other: _____
11 = Institutionalized

13 = Replaced by Symptomatic Therapy Visit

1.3 Were all assessments for this visit completed? (0 = No, 1 = Yes) 1.3 [ ]
If No (0), please note assessments not completed in question 3, Comments.

In addition to the assessments covered by the CRFs specific to this visit, the following tasks were completed at this visit when applicable:

2.1 Status of Concomitant Medication Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported taking any concomitant medications; log is blank) 2.1 [ ]

2.2 Status of Adverse Event Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported any events; log is blank) 2.2 [ ]

2.10 Reviewed Current Medical Conditions Log information and made any necessary changes to the Current Medical Conditions Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported any medical conditions; log is blank) 2.10 |

3. Comments:

_____

_____

_____

I have reviewed the data entries for this visit and determined that they are complete, accurate, and consistent with source documents, if available. All entries were made by me, or by a person who is under my supervision.

INVESTIGATOR'S SIGNATURE	DATE	STAFF CODE

PPMI
ADVERSE EVENT LOG

1 3 2

6 8

SUBJECT ID | | | | | INITIALS | | | | SITE NO | | | |

Record all adverse events that occur during the study visit through designated follow-up period following the study procedures listed below. Record disease entity as AE only if it worsens beyond what investigator expects is within normal range of fluctuation for this subject. Elicit adverse event data by asking an open-ended question, e.g., "What unusual symptoms or medical problems have you experienced since the last visit?" Record any new or change in ongoing sign or symptom as well as any event that has resolved since last evaluation. Enter each change in "severity" on new line. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. IF EVENT IS A SERIOUS ADVERSE EVENT, please refer to the Operations Manual for reporting guidance.

AE # (e.g., 1, 2, etc.)	Adverse Event (Record diagnosis if known)	START DATE (MM/DD/YYYY)	1 = Actual (ACT) 2 = Day Est. (DAY) 3 = Mon/Day Est (MD) 4 = Month Est. (MON)	STOP DATE (MM/DD/YYYY)	1 = Actual (ACT) 2 = Day Est. (DAY) 3 = Mon/Day Est (MD) 4 = Month Est. (MON)	Severity: 1 = mild 2 = moderate 3 = severe	SAE: 0 = No 1 = Yes (If Yes, call Coordination Center)	Relationship to Study*: 1 = unrelated 2 = unlikely 3 = possible 4 = probable 5 = definite	Related to Study Procedure (0 = No 1 = Yes): DaTSCAN	LP	AV-133	Skin Biopsy	[18F] Florbetaben	Other	Check box if this event resulted in withdrawal from the study	Complete when resolved or at Final Visit: Primary Outcome: 1 = recovered 2 = under treatment/ observation 3 = change in AE characteristic 4 = sequelae 5 = fatal 6 = unknown	AE Status at Final Visit: If unresolved, is follow-up required? 0 = No 1 = Yes
			☐		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
			☐		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
			☐		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

* If 3, 4 or 5 are selected, complete "Related to Study Procedure".

INVESTIGATOR'S SIGNATURE DATE STAFF CODE

 (6/24/09)TSO *7/10/14*

PPMI

1 3 2

CURRENT MEDICAL CONDITIONS LOG

7 0

SUBJECT ID | | | | | INITIALS | | | | SITE NO | | | |

INSTRUCTIONS: Enter the sequential row number 1, 2, 3, etc.. **KEY for CATEGORY:**

1d = Dermatological
1e = Ophthalmological
1f = ENT
1g = Pulmonary
1h = Cardiovascular
1i = Gastrointestinal
1j = Hepatobiliary
1k = Renal
1l = Gynecological/Urologic
1m = Musculoskeletal
1n = Metabolic/Endocrine
1o = Hemato/Lymphatic
1p = Neurologic (other than disease under study)
1q = Psychiatric
1r = Allergy/Immunologic – Please note drug allergies
1s = Other

Row #	Category (See KEY above)	Year of Diagnosis (YYYY)	1 = Actual (ACT) 2 = Year Est. (YEAR)	Enter **all current** diagnosed medical conditions. Specify the disorder/diagnosis and use only one line per description. **DO NOT ABBREVIATE.**	Resolved 0 = No 1 = Yes	Year of Resolution (YYYY)

PPMI

CONCOMITANT MEDICATION LOG

1 3 2 | 7 2

SUBJECT ID | INITIALS | SITE NO

Enter all medications taken at Screening Visit. At subsequent visits record new meds, and changes/discontinuation of previously listed meds. Changes in total daily dose or route require a new line. Row: enter 1, 2, 3, etc. Medication: Record generic name; if unknown, enter brand name. For multiple ingredient medications, indicate strength if possible, e.g., carbidopa/levodopa 25/100. Dose: Record dose for each administration. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. Ongoing: Answer yes if medication is still being taken at end of study. Indication: Reason for use, not drug category.

	Row # (e.g., 1, 2, etc.)	MEDICATION (List generic name, if possible)	DOSE	UNITS (e.g., mg, cc, ml, puffs)	FREQUENCY (e.g., qd, BID, qid, etc.)	ROUTE 1 = IV 2 = IM 3 = PO 4 = SC 5 = PR 6 = Sublingual 7 = Inhaled 8 = Topical 9 = Other	START DATE (MM/DD/YYYY)	1 = Actual (ACT) 2 = Day Est. (DAY) 3 = Mon/Day Est (MD) 4 = Month Est. (MON)	STOP DATE (MM/DD/YYYY)	1 = Actual (ACT) 2 = Day Est. (DAY) 3 = Mon/Day Est (MD) 4 = Month Est. (MON)	ONGOING 0 = No 1 = Yes	INDICATION	PD MED? 0 = No, 1 = Yes
SAMPLE	0	paroxetine hydrochloride	20	mg	qd	3	10/30/2003	2	10/31/2003	2	0	depression	0

PPMI

1 3 2 **CONCLUSION OF STUDY PARTICIPATION** 7 4

SUBJECT ID [ ][ ][ ][ ] VISIT NO F N L

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

2. Did the subject complete the study? (00 = No, 01 = Yes) 2. [ ][ ]

If subject prematurely withdrew: 4. [ ][ ]

4. What was the primary reason for withdrawal:
   - 01 = Adverse Event (complete AE Log)
   - 02 = Lost to Follow-up
   - 03 = Subject withdrew consent (specify in 4a)
   - 04 = Pregnancy
   - 05 = Protocol violation
   - 06 = Death of subject
   - 07 = Investigator decision (specify in 4a)
   - 09 = Clinical Monitor decision (specify in 4a)
   - 10 = Sponsor decision (specify in 4a)
   - 11 = Primary Care Physician decision (specify in 4a)
   - 12 = Informant/Caregiver decision (specify in 4a)
   - 13 = Institutionalized
   - 14 = Inability to continue giving consent
   - 15 = Other (specify in 4a)

4a. Specify: _____

5. Date of premature withdrawal:
   (Date investigator deemed the subject would no longer participate in the study) 5. [ ][ ] [ ][ ] [ ][ ][ ][ ]
   MM DD YYYY

PPMI

1 3 2 **SUBJECT SITE TRANSFER FORM** 7 6

SUBJECT ID [ ][ ][ ][ ] VISIT NO [X][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

NOTE: To be completed by the new site.

1. Date of re-consent: 1. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

2. Transferring site number: 2. [ ][ ][ ]

PPMI

1 3 2

WHOLE BLOOD SAMPLE

7 8

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | | | | | | |
MM DD YYYY

1. Whole blood for storage and analysis: (0 = Not collected, 1 = Collected) 1. | |

1a. Date of whole blood collection: 1a. | | | | | | | | |
MM DD YYYY

2. Comments:

_____

_____

_____

PPMI (TAP-PD)

1 3 2 **SUBJECT ELIGIBILITY** 7 8

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

A. ☐ Check box if subject has signed consent.

B. Date informed consent was signed: B. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. PD subject who is otherwise eligible for enrollment into PPMI. 1. [ ]

2. Enrolled at one of three participating sites: 2. [ ]
   - Oregon Health Sciences University, Portland, OR
   - Institute for Neurodegenerative Disorders, New Haven, CT
   - University of Pennsylvania Movement Disorders Center, Philadelphia, PA

3. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 3. [ ]

4. Willing and able to complete additional study procedures. 4. [ ]

To be **ELIGIBLE** for study participation **ALL** answers to items 1-4 must be 1 = Yes.

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Evidence of "atypical" parkinsonian syndromes (e.g. Progressive supranuclear palsy, Multiple system atrophy, drug-induced parkinsonism, Lewy body dementia). 1. [ ]

2. Any medical condition other than PD that would interfere with the subject's ability to perform study procedures as determined by the investigator. 2. [ ]

To be **ELIGIBLE** for study participation **ALL** answers to items 1 and 2 must be 0 = No.

ENROLLMENT

1. Date subject was enrolled into TAP-PD: 1. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

2. Indicate the serial number of the OPDM device sent home with the subject. 2. [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

PPMI (TAP-PD)

1 3 2 **OPDM USE QUESTIONNAIRE** 8 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

Please respond to the questions below to tell us about your experience with the use of the OPDM home dexterity device.

1. How hard was it to understand the directions for using the OPDM dexterity device? 1. ☐
   0 = Not at all hard to understand
   1 = A little bit hard to understand
   2 = Moderately hard to understand
   3 = Very hard to understand

2. How confident were you that you were doing the tasks correctly? 2. ☐
   0 = Not at all confident
   1 = A little bit confident
   2 = Moderately confident
   3 = Very confident

3. Did doing the OPDM dexterity tasks at home fit into your regular schedule? 3. ☐
   0 = It was easy to fit into my day
   1 = I had a little trouble fitting it into my day
   2 = It was moderately difficult to fit into my day
   3 = It was very difficult to fit into my day

4. Did you need to be reminded (by family members or study staff) to complete the OPDM dexterity device tasks? 4. ☐
   0 = Not at all
   1 = Rarely (1 or 2 times)
   2 = Sometimes (3 - 5 times)
   3 = Often (more than 5 times)

5. Did doing the OPDM dexterity tasks at home change the way you felt about participating in the main PPMI study? 5. ☐
   0 = Felt a lot more negative
   1 = Felt a little more negative
   2 = No change
   3 = Felt a little more positive
   4 = Felt a lot more positive

PPMI
SWEDD CONTINUATION

1 3 2 | 8 1

SUBJECT ID | | | | |

VISIT NO C C

INITIALS | | | SITE NO | | | VISIT DATE | | | MM | | DD | | | | | YYYY

2. First extended visit (post V06): 2. | | |

3. Date informed consent signed to continue post 48 months: 3. | | MM | | DD | | | | | YYYY

PPMI
SUBJECT CONTINUATION

1 3 2 | 8 2

SUBJECT ID [ ][ ][ ][ ] VISIT NO C C [ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

2. First extended visit (post V12): 2. [ ][ ][ ]

3. Date informed consent signed to continue post V12: 3. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

PPMI (TAP-PD)

1 3 2 **CONCLUSION OF STUDY PARTICIPATION** 8 4

SUBJECT ID [ ][ ][ ][ ] VISIT NO T A P F N L

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

2. Did the subject complete the study? (00 = No, 01 = Yes) 2. [ ][ ]

If subject prematurely withdrew:

5. Date of premature withdrawal:
(Date investigator deemed the subject would no longer participate in the study) 5. [ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

PPMI

1 3 2 **INCLUSION/EXCLUSION - SWEDD (Amend 4)** 8 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Subjects must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia. 1. ☐

2. A diagnosis of Parkinson disease for 2 years or less at Screening. 2. ☐

3. Hoehn and Yahr Stage I or II at Baseline. 3. ☐

4. Not expected to require PD medication within at least 6 months from Baseline. 4. ☐

5. Male or female age 30 years or older at time of PD diagnosis. 5. ☐

7. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 7. ☐

8. Willing and able to comply with scheduled visits, required study procedures and laboratory tests. 8. ☐

9. Women may not be pregnant, lactating or planning pregnancy during the course of the study. 9. ☐

11. Confirmation from imaging core that screening dopamine transporter SPECT scan is consistent with no dopamine transporter deficit (or for sites only conducting PET scan that VMAT-2 PET scan shows no evidence of VMAT deficit). 11. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-5 , 7, 8 and 11 must be **1 = Yes** and item 9 must be **1 = Yes** if female of child bearing potential

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g., Wilson's disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy). 1. ☐

2. Currently taking levodopa, dopamine agonists, MAO-B inhibitors, (e.g. selegiline, rasagiline) amantadine or other PD medication. 2. ☐

SUBJECT ID | | | | | VISIT NO | | | |

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes) Continued

3.	Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline.	3.
4.	Has taken levopdopa or dopamine agonists prior to Baseline for more than a total of 60 days.	4.
5.	A clinical diagnosis of dementia as determined by the investigator.	5.
6.	Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening.	6.
7.	Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture.	7.
8.	Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia.	8.
9.	Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.	9.
10.	Use of investigational drugs or devices within 60 days prior to Baseline (dietary supplements taken outside of a clinical trial are not exclusionary, e.g., coenzyme Q10).	10.
11.	Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator).	11.

To be **ELIGIBLE** for study participation **ALL** answers to items 1-11 must be **0 = No**

To discuss questionable subject eligibility, call the CTCC Project Manager.

PROTOCOL DEVIATION CODE

PPMI

1 3 2 **CLINICAL DIAGNOSIS AND MANAGEMENT QUESTIONNAIRE** 8 8

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

1. To what degree are you confident that this person has motor signs consistent with a parkinsonian syndrome (PS) (any condition in which there is neurodegeneration of dopaminergic cells in the substantia nigra)? 1. [ ]

1 = Motor abnormalities that are likely signs of PS (90-100%)
2 = Motor abnormalities that may be signs of PS (50-89%)
3 = Non-specific motor abnormalities (10-49%)
4 = No evidence of parkinsonian motor signs (0-9%)

2. Indicate the following signs on examination that you believe are related to a PS (any condition in which there is neurodegeneration of dopaminergic cells in the substantia nigra). (0 = No, 1 = Yes)

2a. No motor signs consistent with PS 2a. [ ]
2b. Rest tremor 2b. [ ]
2c. Rigidity 2c. [ ]
2d. Bradykinesia 2d. [ ]
2e. Gait disturbances 2e. [ ]
2f. Other (specify)_____ 2f. [ ]

3. Indicate the current most likely clinical diagnosis from one of the categories listed below (choose one): 3. [ ][ ]

Disorders expected to have a dopamine transporter deficit.

01 = Idiopathic PD
04 = Corticobasal ganglionic degeneration
05 = Dementia with Lewy bodies
08 = Hemiparkinsonism/hemiatrophy syndrome
11 = Multiple system atrophy
14 = Progressive supranuclear palsy

Disorders expected to have no dopamine transporter deficit.

02 = Alzheimer disease
03 = Chromosome 17 frontotemporal dementia
06 = Dopa-responsive dystonia
07 = Essential tremor
09 = Juvenile autosomal recessive parkinsonism
10 = Motor neuron disease with parkinsonism
12 = Neuroleptic-induced parkinsonism
13 = Normal pressure hydrocephalus
15 = Psychogenic illness
16 = Vascular parkinsonism
17 = No PD nor other neurological disorder
18 = Spinocerebellar Ataxia (SCA)
97 = Other neurological disorder(s) (specify)_____

1 3 2 **CLINICAL DIAGNOSIS AND MANAGEMENT QUESTIONNAIRE** 8 8

SUBJECT ID | | | | | VISIT NO | | | |

4. Has there been a change in the clinical diagnosis of this subject since the last visit? (0 = No, 1 = Yes) 4. ☐

If Yes (1) to question 4, indicate all factors that have been most influential in your current diagnosis: (0 = No, 1 = Yes)

4a. Dopamine transporter imaging information 4a. ☐

4b. Clinical signs 4b. ☐

4c. Response/lack of response to PD medication 4c. ☐

4d. Natural history of condition (i.e. rapid progression, lack of progression) 4d. ☐

4e. Other (specify)_____ 4e. ☐

5. Has there been a change in the clinical management of this subject since the last visit? (0 = No, 1 = Yes) 5. ☐

6. Current management for this subject includes: (0 = No, 1 = Yes)

6a. Management aimed at treating symptoms of PD, including dopamine replacement therapy, anticholinergics, MAO-B inhibitor 6a. ☐

6b. Enrolled in a treatment trial for PD 6b. ☐

6c. Management aimed at treating a condition other than PD or PS not associated with a dopamine transporter deficit 6c. ☐

6d. Additional diagnostic testing 6d. ☐

6e. No treatment necessary 6e. ☐

7. Has the subject seen another neurologist since the last visit? (0 = No, 1 = Yes) 7. ☐

7a. If yes, what is that neurologist's working diagnosis? (specify) _____

PPMI

1 3 2 **[^{18}F] Florbetaben - PPMI ELIGIBILITY** 1 2 1

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. ☐ Check box if subject signed consent to participate in the [^{18}F] Florbetaben-PPMI companion protocol.

B. Date informed consent for participation in [^{18}F] Florbetaben-PPMI companion protocol was signed: B. | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Subject is currently enrolled in PPMI. 1. ☐

To be **ELIGIBLE** for study participation item 1 must be 1 = YES

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Any contraindication to have a PET scan performed. 1. ☐

2. Known intolerance to the PET tracer [^{18}F] Florbetaben and/or its excipients. 2. ☐

3. Currently pregnant or lactating. 3. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-3 must be **0 = No**

PPMI

1 3 2 **[^{18}F] Florbetaben - PPMI TELEPHONE FOLLOW-UP** 1 2 2

SUBJECT ID | | | | | VISIT NO | F | L | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

INSTRUCTIONS: To be used for follow-up Telephone call to subject.

1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. ☐

1a. ☐

1a. If No (0), please indicate the reason:
1 = phone disconnected
2 = multiple messages left on answering machine were not returned
3 = subject moved - unable to locate

5 = other (specify)_____

If new contact information obtained for the subject (e.g., change of phone number or address) document the new contact information in the subject's study record and Confidential Subject Identification Log.

During the telephone contact:

- Review and record concomitant medications
- Review and record adverse events

2. Comments:

_____

_____

_____

PPMI

1 3 2 **[^{18}F] Florbetaben - PPMI IMAGING** 1 2 3

SUBJECT ID | | | | | VISIT NO | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

VITAL SIGNS MEASURED APROXIMATELY 5 MINUTES PRIOR TO INJECTION

1. Time vital signs measured prior to injection: (24-hour clock) 1. | | | : | |

2. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for
1-3 minutes) 2. | | | / | | |

3. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 3. | | |

4. If female of childbearing potential, was urine pregnancy test performed?
(0 = No, 1 = Yes) 4. |

4a. Indicate the result of the urine pregnancy test:
(0 = Negative, 1 = Positive) 4a. |

4b. Was the result of the urine pregnancy test confirmed prior to [^{18}F] Florbetaben injection? (0 = No, 1 = Yes) 4b. |

Note:
Women of childbearing potential must have a negative urine pregnancy test result prior to injection.

SUBJECT ID | | | | | VISIT NO | | | |

VITAL SIGNS MEASURED APPROXIMATELY 15 MINUTES POST-INJECTION

5. Time vital signs measured after [18F] Florbetaben injection: (24-hour clock) 7. | | : | |

6. Supine blood pressure: systolic/diastolic (mmHg) (to be taken after subject has been supine for 1-3 minutes) 6. | | | / | | |

7. Supine heart rate (beats per minute) (to be taken after subject has been supine for 1-3 minutes) 7. | | |

8. [18F] Florbetaben PET imaging scan: (0 = Not Completed, 1 = Completed) 8. |

8a. Date [18F] Florbetaben PET imaging scan was completed: 8a. | | MM | | DD | | | | YYYY

9. [18F] Florbetaben imaging data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes) 9. |

Comments:

_____

_____

_____

PPMI

1 3 2

CONTACT INFORMATION- FOUND

1 3 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Did the subject agree to share contact information with the University of California San Francisco (UCSF) for the FOUND protocol? (0 = No, 1 = Yes) 1. | |

1a. Date contact information was obtained: 1a. | | | MM | | DD | | | | | YYYY

1b. Date contact form sent to UCSF: 1b. | | | MM | | DD | | | | | YYYY

PPMI
RESEARCH ADVANCE DIRECTIVE

1 3 2 | 1 3 1

SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

INITIALS [ ][ ][ ] SITE NO [ ][ ][ ] VISIT DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

1. Status of Research Advance directive:
(1 = Initial, 2 = Continued, 3 = Declined, 4 = Withdrew) 1. [ ]

1a. If q1 response is 1 or 4, on what date was the Research Advance directive completed or withdrawn? 1a. [ ][ ] [ ][ ] [ ][ ][ ][ ]
MM DD YYYY

PPMI

1 3 2 **SKIN BIOPSY ELIGIBILITY (PD - HC)** 1 4 0

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. ☐ Check box if subject signed consent to participate in the skin biopsy companion protocol.

B. Date informed consent for participation in skin biopsy companion protocol was signed: B. | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Currently enrolled in the PPMI study 1. ☐

2. Is a subject with idiopathic PD, PD or unaffected subject with a LRRK2 or SNCA mutation, or is a healthy control subject in PPMI 2. ☐

3. Is able and willing to provide written informed consent in accordance with Good Clinical Practice(GCP), International Conference on Harmonization (ICH), and local regulations 3. ☐

4. Is able and willing to comply with study procedures 4. ☐

To be **ELIGIBLE** for study participation ALL items 1 - 4 must be 1 = YES

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Has a history of keloid formation (unless keloid formation resulted from a skin biopsy that was required as part of routine medical care) 1. ☐

2. Is currently receiving treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of a biopsy 2. ☐

3. Has a bleeding disorder that would preclude biopsy 3. ☐

4. In the investigator's judgement, any other reason that the individual should not participate (e.g., subject has an infectious disease or is in an immune compromised state (HIV, pregnancy, tuberculosis, etc.)) 4. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-4 must be **0 = No**

PPMI
SKIN BIOPSY

1 3 2 | 1 4 1

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

1. Was biopsy completed? (0 = No, 1 = Yes) (If No, comment below) 1. |

2. Was anesthesia administered? (0 = No, 1 = Yes) 2. |

3. Location of biopsy: 3. |
   1 = upper arm
   2 = lower arm
   3 = upper leg
   4 = lower leg
   5 = other (specify) _____

3a. On which side of the body was the biopsy performed? 3a. |
   1 = right
   2 = left

4. Were there any complications during the biopsy? (0 = No, 1 = Yes) (If Yes, comment below) (If complication was an adverse event, please remember to document event on the Adverse Event log.) 4. |

5. What type of wound closure was used? 5. |
   1 = dressing only
   2 = steri strips
   3 = suture
   4 = other (specify) _____

6. Time that biopsy was collected: 6 | | : | | (24hr clock)

7. Time biopsy specimen was refrigerated: 7. | | : | | (24hr clock)

8. Date sample shipped to NYSCF: 8. | | (MM) | | (DD) | | | | | (YYYY)

Comments: _____

_____

_____

_____

PPMI

1 3 2 **SKIN BIOPSY TELEPHONE FOLLOW-UP** 1 4 2

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

INSTRUCTIONS: To be used for follow-up Telephone call to subject.

1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. ☐

1a. ☐

1a. If No (0), please indicate the reason:
1 = phone disconnected
2 = multiple messages left on answering machine were not returned
3 = subject moved - unable to locate

5 = other (specify)_____

If new contact information obtained for the subject (e.g., change of phone number or address) document the new contact information in the subject's study record and Confidential Subject Identification Log.

During the telephone contact:

- Review and record concomitant medications
- Review and record adverse events

2. Comments:

_____

_____

_____

PPMI

CONSENT/WITHDRAWAL OF CONSENT FOR FUTURE PROCEDURES

1 3 2

1 8 4

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

1. Subject consented to be contacted by site staff about future research studies? (1 = Initial Consent, 2 = Continued Consent, 3 = Declined Participation, 4 = Withdrew Consent) 1. | |

1a. If question 1 is 1 or 4, on what date was consent obtained or withdrawn: 1a. | | | MM | | DD | | | | | YYYY

PPMI

1 3 2

COGNITIVE ASSESSMENTS

1 8 5

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | (MM) | | (DD) | | | | | (YYYY)

Time administered:

1. HVLT-R Immediate Recall (24-hour clock) — 1. | | | : | | |
2. HVLT-R Delayed Recall/Recognition (24-hour clock) — 2. | | | : | | |
3. Benton Judgment of Line Orientation (24-hour clock) — 3. | | | : | | |
4. Semantic Fluency (24-hour clock) — 4. | | | : | | |
5. Letter Number Sequencing (24-hour clock) — 5. | | | : | | |
6. Symbol Digit Modalities (24-hour clock) — 6. | | | : | | |

Comments:

_____

_____

_____

PPMI

1 3 2 **SURGERY FOR PARKINSON DISEASE** 1 8 7

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

A. Have you had surgery for your Parkinson disease since your last visit? A. | |
(0 = No, 1 = Yes)
If Yes, please complete the rest of this form.

1. Date (or estimated date) of surgery for Parkinson disease 1. | | | MM | | | | | YYYY

2. Type of surgery 2. | |
1 = DBS (Deep Brain Stimulation)
2 = Levodopa intestinal gel infusion
3 = Other, specify_____
4 = Unknown

3. Side 3. | |
1 = Bilateral
2 = Left
3 = Right
4 = Not applicable (e.g., for levodopa intestinal gel infusion)
5 = Unknown

4. Location (check all that apply)
- ☐ GPi (Globus pallidus internal segment)
- ☐ STN (subthalmic nucleus)
- ☐ Other, specify _____
- ☐ Not applicable (e.g., for levodopa intestinal gel infusion)
- ☐ Unknown

Comments: _____

_____

_____

_____

PPMI
iPSC ELIGIBILITY

1 3 2 | 2 0 1

SUBJECT ID | VISIT NO

INITIALS | SITE NO | VISIT DATE (MM / DD / YYYY)

1. Check box if subject signed consent to participate in the iPSC companion protocol. ☐

2. Date informed consent for participation in iPSC companion protocol was signed: 2. (MM / DD / YYYY)

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

3. Currently enrolled in the PPMI study. 3. ☐

4. Is able and willing to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 4. ☐

5. Is able and willing to comply with study procedures. 5. ☐

To be **ELIGIBLE** for study participation **ALL** items 3-5 must be **1 = Yes.**

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Has a history of bone marrow transplant. 1. ☐

2. Undergoes regular blood transfusions. 2. ☐

3. In the Investigator's judgement, any other reason that the individual should not participate. 3. ☐

To be **ELIGIBLE** for study participation **ALL** items 1-3 must be **0 = No.**

PPMI

1 3 2 **iPSC BLOOD SAMPLE** 2 0 2

SUBJECT ID _____ VISIT NO _____

INITIALS _____ SITE NO _____ VISIT DATE MM _____ DD _____ YYYY _____

1. Was blood draw completed? (0 = No, 1 = Yes) (If No, comment below) 1. _____

2. Is subject on medication for PD? (0 = No, 1 = Yes) 2. _____

   2a. Date of most recent PD medication dosing: 2a. MM _____ DD _____ YYYY _____

   2b. Time of most recent PD medication dosing: (24-hour clock) 2b. _____ : _____

3. Did subject take warfarin (Coumadin) prior to blood draw today? (0 = No, 1 = Yes) 3. _____

4. Did subject take heparin or any other similar anticoagulant medication prior to blood draw today? (0 = No, 1 = Yes) 4. _____

5. Does the subject have a history of liver disease? (0 = No, 1 = Yes) 5. _____

6. Does the subject have a history of multiple myeloma? (0 = No, 1 = Yes) 6. _____

7. Blood for Lithium Heparin: (0 = Not Collected, 1 = Collected) 7. _____

   7a. Time of Lithium Heparin sample collection: (24-hour clock) 7a. _____ : _____

   7b. Number of Inversions: 7b. _____

PPMI

1 3 2 **iPSC BLOOD SAMPLE** 2 0 2

SUBJECT ID [ ][ ][ ][ ][ ] VISIT NO [ ][ ][ ]

8. Blood for Serum Separated Tube sample collection: (0 = Not Collected, 1 = Collected) 8. [ ]

8a. Time of Serum Separated Tube sample collection: (24-hour clock) 8a. [ ][ ] : [ ][ ]

8b. Time of centrifugation: (24-hour clock) 8b. [ ][ ] : [ ][ ]

8c. Rate of centrifugation: (xg) 8c. [ ][ ][ ][ ]

8d. Duration of centrifugation: (minutes) 8d. [ ][ ]

8e. Was sample spun at room temperature? (0 = No, 1 = Yes) 8e. [ ]

9. Blood for (CPT): (0 = Not Collected, 1 = Collected) 9. [ ]

9a. Number of CPT tubes collected: 9a. [ ]

9b. Time of CPT sample collection: (24-hour clock) 9b. [ ][ ] : [ ][ ]

9c. Time of centrifugation: (24-hour clock) 9c. [ ][ ] : [ ][ ]

9d. Rate of centrifugation: (xg) 9d. [ ][ ][ ][ ]

9e. Duration of centrifugation: (minutes) 9e. [ ][ ]

9f. Was sample spun at room temperature? (0 = No, 1 = Yes) 9f. [ ]

10. Date samples shipped: 10. [ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

11. Cold gel packs used for shipping: (0 = No, 1 = Yes) 11. [ ]

12. CDI ID#: 9c. [ ][ ][ ][ ][ ] . 1

Comments: _____

_____

_____