

PPMI

1 3 2

PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)

0 0

SUBJECT ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	<input type="text"/>	<input type="text"/>	<input type="text"/>					
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT DATE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
								MM		DD			YYYY

**PHYSICAL ACTIVITY SCALE
FOR THE ELDERLY
(P A S E)**



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PPMI

1 3 2

PHYSICAL ACTIVITY SCALE FOR THE ELDERLY (PASE)

0 0

SUBJECT ID

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VISIT NO

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New England
Research Institutes, Inc.

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

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.

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

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

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

SUBJECT ID

VISIT NO

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.

	<u>NO</u>	<u>YES</u>
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

SUBJECT ID

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VISIT NO

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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

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VISIT NO

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**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:
(1 = Parkinson disease, 2 = Healthy Control, 3 = SWEDD, 4 = Prodromal)

C. []

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

C1. []

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)?
(0 = No, 1 = Yes, 2 = Unknown or not reported)

3. []

RACE

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

4.1 []

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

4.2 []

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

4.3 []

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

4.4 []

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

4.5 []

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

4.6 []

PPMI

1 3 2

SCREENING/DEMOGRAPHICS

0 2

SUBJECT ID

Four empty boxes for subject ID

SITE NO

Three empty boxes for site number

5. Projected Enrollment Date:

5. MM DD YYYY date input fields

6. Referral Source:

- 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:

Horizontal line for name input

7a. Declined

7b. Reason for declining:

- 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)

7b. Two empty boxes

8a. Excluded

8b. Reason for exclusion:

- 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)

8b. Two empty boxes

Comments:

Two horizontal lines for comments

PPMI

SOCIO-ECONOMICS

1	3	2
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0	4
---	---

SUBJECT ID

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VISIT NO

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INITIALS

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SITE NO

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VISIT DATE

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MM

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YYYY

1. Subject Education (number of years)

1.

--	--

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

4.

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PPMI

CTCC UNIQUE ID

1	3	2
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0	6
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SUBJECT ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	<input type="text"/>	<input type="text"/>	<input type="text"/>					
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	VISIT DATE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
							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.

PPMI

1 3 2

INCLUSION/EXCLUSION - PARKINSON DISEASE (Amend 4)

1 0

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 levodopa 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 methyl dopa, 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

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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)

1	3	2
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1	0
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SUBJECT ID

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VISIT NO

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

- | | | | |
|-----|---|-----|--------------------------|
| 5. | A clinical diagnosis of dementia as determined by the investigator. | 5. | <input type="checkbox"/> |
| 6. | Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyl dopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening. | 6. | <input type="checkbox"/> |
| 7. | Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture. | 7. | <input type="checkbox"/> |
| 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. | <input type="checkbox"/> |
| 9. | Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation. | 9. | <input type="checkbox"/> |
| 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. | <input type="checkbox"/> |
| 11. | Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator). | 11. | <input type="checkbox"/> |
| 16. | Current or active clinically significant neurological disorder or psychiatric disorder (in the opinion of the Investigator). | 16. | <input type="checkbox"/> |
| 17. | GDS score greater than or equal to 10, or GDS score of 5 - 9 without Investigator discretion to enter study. | 17. | <input type="checkbox"/> |
| 18. | STAI Form Y-1 greater than or equal to 54 without Investigator discretion to enter study. | 18. | <input type="checkbox"/> |
| 19. | A clinical diagnosis of Parkinson disease at the Screening visit as determined by the Investigator. | 19. | <input type="checkbox"/> |

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 methyl dopa, 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.

PPMI

1 3 2

INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)

1 1

SUBJECT ID

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VISIT NO

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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.

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PROTOCOL DEVIATION CODE

PPMI

1 3 2

AV-133 ELIGIBILITY

1 1

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
MM

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YYYY

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

B. Date informed consent for participation in ¹⁸F-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 ¹⁸F-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 ¹⁸F-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 ¹⁸F-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

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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. If No (0), please indicate the reason: 1a. []
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

AV-133 TELEPHONE FOLLOW-UP

1 3

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. If No (0), please indicate the reason: 1a.

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

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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 [][]
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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 [][][]
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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

PPMI

1 3 2

DIAGNOSTIC FEATURES (PD)

1 7

SUBJECT ID

VISIT NO

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 | <input type="text"/> |
| 7.2 | Bradykinesia is absent | 7.2 | <input type="text"/> |
| 7.3 | Pure Akinesia (without rigidity or tremor) | 7.3 | <input type="text"/> |
| 7.4 | Bradykinesia does not completely account for difficulty with rapid successive movements (e.g., apraxia, ataxia, pyramidal tract dysfunction) | 7.4 | <input type="text"/> |
| 7.5 | Other, specify: _____ | 7.5 | <input type="text"/> |
| 8. | Postural or gait disturbances: | | |
| 8.1 | Postural and gait disturbances are completely typical of PD | 8.1 | <input type="text"/> |
| 8.2 | Wide-based gait or ataxia | 8.2 | <input type="text"/> |
| 8.3 | Prominent freezing early in course | 8.3 | <input type="text"/> |
| 8.4 | Likely to fall if not extra careful | 8.4 | <input type="text"/> |
| 8.5 | Other, specify: _____ | 8.5 | <input type="text"/> |
| 9. | Mental Changes: | | |
| 9.1 | Psychiatric | 9.1 | <input type="text"/> |
| 9.2 | Cognitive | 9.2 | <input type="text"/> |
| 10. | Other hyperkinesias (not related to levodopa or agonists): | | |
| 10.1 | Dystonia | 10.1 | <input type="text"/> |
| 10.2 | Chorea | 10.2 | <input type="text"/> |
| 10.3 | Myoclonus (include stimulus-induced) | 10.3 | <input type="text"/> |
| 10.4 | Other (e.g., alien limbs): _____ | 10.4 | <input type="text"/> |
| 11. | Presence of body hemiatrophy | 11. | <input type="text"/> |
| 12. | Autonomic disturbances: | | |
| 12.1 | Postural hypotension | 12.1 | <input type="text"/> |
| 12.2 | Sexual dysfunction | 12.2 | <input type="text"/> |
| 12.3 | Urinary dysfunction | 12.3 | <input type="text"/> |
| 12.4 | Bowel dysfunction | 12.4 | <input type="text"/> |

PPMI

1 3 2

DIAGNOSTIC FEATURES (PD)

1 7

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
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MEDICAL HISTORY (GENERAL)

1 3 2

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? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1e.	Ophthalmological History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		
1f.	ENT History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
		2.		
		3.		
		4.		

PPMI

MEDICAL HISTORY (GENERAL)

1 3 2

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
1g. Pulmonary History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1h. Cardiovascular History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1i. Gastrointestinal History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

PPMI

MEDICAL HISTORY (GENERAL)

1 3 2

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
1j. Hepatobiliary History? <input type="checkbox"/> (0 = None, 1 = Yes)	1. 2. 3. 4.		
1k. Renal History? <input type="checkbox"/> (0 = None, 1 = Yes)	1. 2. 3. 4.		
1l. Gynecologic/ Urologic History? <input type="checkbox"/> (0 = None, 1 = Yes)	1. 2. 3. 4.		

PPMI

MEDICAL HISTORY (GENERAL)

1 3 2

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	1.		
	History?	2.		
	<input type="checkbox"/>	3.		
	(0 = None, 1 = Yes)	4.		
1n.	Metabolic/ Endocrine	1.		
	History?	2.		
	<input type="checkbox"/>	3.		
	(0 = None, 1 = Yes)	4.		
1o.	Hemato/Lymphatic	1.		
	History?	2.		
	<input type="checkbox"/>	3.		
	(0 = None, 1 = Yes)	4.		

PPMI

MEDICAL HISTORY (GENERAL)

1 3 2

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? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1q. Psychiatric History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1r. Allergy/ Immunologic Please note drug allergies History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

PPMI

MEDICAL HISTORY (GENERAL)

1 3 2

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
1s. Other History? <input type="checkbox"/> (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			
<input type="text"/> <input type="text"/>	A.		
<input type="text"/> <input type="text"/>	B.		
<input type="text"/> <input type="text"/>	C.		
<input type="text"/> <input type="text"/>	D.		
<input type="text"/> <input type="text"/>	E.		
<input type="text"/> <input type="text"/>	F.		
<input type="text"/> <input type="text"/>	G.		

**PPMI
FAMILY HISTORY (PD)**

1 3 2

2 0

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE

MM DD

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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. []

PPMI

1 3 2

GENERAL NEUROLOGICAL EXAM

2 2

SUBJECT ID [][][][]

VISIT NO [][][]

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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PPMI

1 3 2

GENERAL PHYSICAL EXAM

2 4

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
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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. []

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1	3	2
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GENERAL PHYSICAL EXAM

2	4
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SUBJECT ID

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VISIT NO

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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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VITAL SIGNS

1 3 2

2 6

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
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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:

PPMI

PREGNANCY FORM

1	3	2
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2	8
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SUBJECT ID

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VISIT NO

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INITIALS

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SITE NO

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VISIT DATE

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YYYY

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

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

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

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

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YYYY

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

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? 3. []
(0 = No, 1 = Yes)

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. [][] : [][]

PPMI

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
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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 []

3.10 Gait []

3.2 Facial expression []

3.11 Freezing of gait []

3.3a Rigidity - Neck []

3.12 Postural stability []

3.3b Rigidity - RUE []

3.13 Posture []

3.3c Rigidity - LUE []

3.14 Global spontaneity of movement []

3.3d Rigidity - RLE []

3.15a Postural tremor - Right hand []

3.3e Rigidity - LLE []

3.15b Postural tremor - Left hand []

3.4a Finger Tapping Right Hand []

3.16a Kinetic tremor - Right hand []

3.4b Finger Tapping Left Hand []

3.16b Kinetic tremor - Left hand []

3.5a Hand movements - Right Hand []

3.17a Rest tremor amplitude - RUE []

3.5b Hand movements - Left Hand []

3.17b Rest tremor amplitude - LUE []

3.6a Pronation - Supination Movements - Right Hand []

3.17c Rest tremor amplitude - RLE []

3.6b Pronation - Supination Movements - Left Hand []

3.17d Rest tremor amplitude - LLE []

3.7a Toe tapping - Right foot []

3.17e Rest tremor amplitude - Lip/jaw []

3.7b Toe tapping - Left foot []

3.18 Constancy of rest []

3.8a Leg agility - Right leg []

3.19 Were dyskinesias present [] No [] Yes

3.8b Leg agility - Left leg []

3.20 Did these movements interfere with ratings [] No [] Yes

3.9 Arising from chair []

3.21 Hoehn and Yahr Stage []

Examiner [][][][]

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PPMI

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 HVLTR 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 related false - positive errors 1.6
 - 1.7 Delayed recognition - # of unrelated false - positive errors 1.7

2. Indicate the HVLTR 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: _____

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SEMANTIC FLUENCY

1	3	2
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3	8
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SUBJECT ID

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VISIT NO

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INITIALS

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SITE NO

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VISIT DATE

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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. <input type="text"/>
1b.	6 - P (6 - P)		1b. <input type="text"/>
1c.	B - 5 (5 - B)		1c. <input type="text"/>
2a.	F - 7 - L (7 - F - L)		2a. <input type="text"/>
2b.	R - 4 - D (4 - D - R)		2b. <input type="text"/>
2c.	H - 1 - 8 (1 - 8 - H)		2c. <input type="text"/>
3a.	T - 9 - A - 3 (3 - 9 - A - T)		3a. <input type="text"/>
3b.	V - 1 - J - 5 (1 - 5 - J - V)		3b. <input type="text"/>
3c.	7 - N - 4 - L (4 - 7 - L - N)		3c. <input type="text"/>
4a.	8 - D - 6 - G - 1 (1 - 6 - 8 - D - G)		4a. <input type="text"/>
4b.	K - 2 - C - 7 - S (2 - 7 - C - K - S)		4b. <input type="text"/>
4c.	5 - P - 3 - Y - 9 (3 - 5 - 9 - P - Y)		4c. <input type="text"/>

PPMI

1 3 2

LETTER - NUMBER SEQUENCING (PD)

4 0

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. <input type="text"/>
5b.	W - 8 - H - 5 - F - 3 (3 - 5 - 8 - F - H - W)		5b. <input type="text"/>
5c.	6 - G - 9 - A - 2 - S (2 - 6 - 9 - A - G - S)		5c. <input type="text"/>
6a.	R - 3 - B - 4 - Z - 1 - C (1 - 3 - 4 - B - C - R - Z)		6a. <input type="text"/>
6b.	5 - T - 9 - J - 2 - X - 7 (2 - 5 - 7 - 9 - J - T - X)		6b. <input type="text"/>
6c.	E - 1 - H - 8 - R - 4 - D (1 - 4 - 8 - D - E - H - R)		6c. <input type="text"/>
7a.	5 - H - 9 - S - 2 - N - 6 - A (2 - 5 - 6 - 9 - A - H - N - S)		7a. <input type="text"/>
7b.	D - 1 - R - 9 - B - 4 - K - 3 (1 - 3 - 4 - 9 - B - D - K - R)		7b. <input type="text"/>
7c.	7 - M - 2 - T - 6 - F - 1 - Z (1 - 2 - 6 - 7 - F - M - T - Z)		7c. <input type="text"/>

PPMI

1 3 2

SYMBOL DIGIT MODALITIES TEST

4 2

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
MM

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DD

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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

EPWORTH SLEEPINESS SCALE

1 3 2

4 4

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
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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. []

SUBJECT ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	<input type="text"/>	<input type="text"/>	<input type="text"/>
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	VISIT DATE	<input type="text"/>
							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.

SUBJECT ID

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VISIT NO

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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

GERIATRIC DEPRESSION SCALE (Short Version)

1 3 2

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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	<input type="text"/>	<input type="text"/>	<input type="text"/>
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
				VISIT DATE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					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

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VISIT NO

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**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

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VISIT NO

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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

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VISIT NO

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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?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

16. Have you fainted in the past 6 months?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
never	sometimes	regularly	often

SUBJECT ID

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VISIT NO

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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)?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| never | sometimes | regularly | often | <i>not applicable</i> |
23. In the past month, how often have you been unable to ejaculate?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| never | sometimes | regularly | often | <i>not applicable</i> |
- 23a. In the past month, have you taken medication for an erection disorder? (If so, which medication?)
- | | |
|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> |
| 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?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| never | sometimes | regularly | often | <i>not applicable</i> |
25. In the past month, have you had difficulty reaching an orgasm?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| never | sometimes | regularly | often | <i>not applicable</i> |

SUBJECT ID

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VISIT NO

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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:

© This questionnaire is made available free of charge, with the permission of the authors, to all those undertaking non-profit and profit making research. Future users may be requested to share data for psychometric purposes. Use of this questionnaire in studies should be communicated to the developers. No changes may be made to the questionnaire without written permission. Please use the following reference in publications:

Visser M, Marinus J, Stiggebout 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.

SUBJECT ID

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VISIT NO

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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.

SUBJECT ID

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VISIT NO

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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
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5	6
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SUBJECT ID

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VISIT NO

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INITIALS

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SITE NO

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VISIT DATE

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MM

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YYYY

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

--

1a. Date blood sample for DNA collected:

1a.

--	--

MM

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YYYY

2. Volume of blood collected: (milliliters)

2.

--	--

3. Date DNA sample shipped:

3.

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MM

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YYYY

PPMI

LABORATORY PROCEDURES

1 3 2

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.

PPMI

LABORATORY PROCEDURES

1	3	2
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5	8
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SUBJECT ID

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VISIT NO

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(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.

--	--

 :

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

--	--

Comments:

PPMI

CLINICAL LABS

1 3 2

5 9

SUBJECT ID [][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
MM

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[][][][]
YYYY

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

1. []

1a. Date shipped to central lab:

1a. [][]
MM

[][]
DD

[][][][]
YYYY

Comments:

PPMI

MAGNETIC RESONANCE IMAGING

1 3 2

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

DaTSCAN IMAGING

1 3 2

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? A.
 (0 = No, 1 = Yes)
 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 4.
 (screening Only)? (0 = No, 1 = Yes)
- 4a. Indicate the result of the serum pregnancy test: 4a.
 (0 = Negative, 1 = Positive)
- 4b. Was the result of the serum pregnancy test confirmed prior to the first 4b.
¹⁸F-AV-133 injection? (0 = No, 1 = Yes)
5. If female of childbearing potential, was urine pregnancy test performed? 5.
 (0 = No, 1 = Yes)
- 5a. Indicate the result of the urine pregnancy test: 5a.
 (0 = Negative, 1 = Positive)
- 5b. Was the result of the urine pregnancy test confirmed prior to ¹⁸F-AV-133 5b.
 injection? (0 = No, 1 = Yes)

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 ¹⁸F-AV-133 injection: (24-hour clock) 6. :

PPMI

1 3 2

AV-133 IMAGING

6 3

SUBJECT ID [][][][]

VISIT NO [][][]

VITAL SIGNS MEASURED APPROXIMATELY 15 MINUTES POST-INJECTION

7. Time vital signs measured after 18F-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

LUMBAR PUNCTURE

1 3 2

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

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

PPMI

LUMBAR PUNCTURE

1	3	2
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6	4
---	---

SUBJECT ID

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VISIT NO

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4. Indicate method of collecting the CSF: 4.

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 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.

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 :

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

--	--

9. Time CSF was centrifuged: (24-hour clock) 9.

--	--

 :

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 (Within 15 minutes from sample collection)

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

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

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

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 :

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

--	--

14. Total number of aliquot tubes: 14.

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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.

--	--

 :

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 (24-hour clock)

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

-		
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17. Was part of the sample sent to local lab for analyses? (0 = No, 1 = Yes) 17.

--

 If No, specify in Comments.

PPMI

LUMBAR PUNCTURE

1 3 2

6 4

SUBJECT ID [][][][]

VISIT NO [][][]

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

18. [][][][]

Per cubic millimeter Per microliter Per liter Other_____

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

19. [][][][]

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

SIGNATURE FORM

1 3 2

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 []

PPMI

SIGNATURE FORM

1 3 2

6 6

SUBJECT ID [][][][]

VISIT NO [][][]

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)	STOP DATE (MM/DD/YYYY)	Severity	SAE	Relationship to Study*	Related to Study Procedure						Check box if this event resulted in withdrawal from the study	Complete when resolved or at Final Visit	
							DaTSCAN	LP	AV-133	Skin Biopsy	[¹⁸ F] Florbetaben	Other		Primary Outcome	AE Status at Final Visit

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

INVESTIGATOR'S SIGNATURE

DATE

STAFF CODE

1 3 2

PPMI

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	7	2
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SUBJECT ID	INITIALS	SITE NO	
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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)	STOP DATE (MM/DD/YYYY)	1 = Actual (ACT) 2 = Day Est. (DAY) 3 = Mon/Day Est (MD) 4 = Month Est. (MON)	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
0	paroxetine hydrochloride	20	mg	qd	3	10/30/2003	10/31/2003	2	2	0	depression	0
					<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
					<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
					<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
					<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>

SAMPLE

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. What was the primary reason for withdrawal:

4. [][]

- 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
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OPDM USE QUESTIONNAIRE

8	0
---	---

SUBJECT ID

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 VISIT NO

--	--	--

INITIALS

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 SITE NO

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 VISIT DATE

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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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	C	C	<input type="text"/>
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
				VISIT DATE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					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

1 3 2

SUBJECT CONTINUATION

8 2

SUBJECT ID

VISIT NO V 1 2

INITIALS

SITE NO

VISIT DATE
MM

DD

YYYY

A. Did subject agree to continue in PPMI beyond visit 12 (month 60)?
(0 = No, 1 = Yes)

A.

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: 5.
(Date investigator deemed the subject would no longer participate in the study)
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.

PPMI

1 3 2

INCLUSION/EXCLUSION - SWEDD (Amend 4)

8 6

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. <input type="checkbox"/> |
| 4. | Has taken levodopa or dopamine agonists prior to Baseline for more than a total of 60 days. | 4. <input type="checkbox"/> |
| 5. | A clinical diagnosis of dementia as determined by the investigator. | 5. <input type="checkbox"/> |
| 6. | Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyl dopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening. | 6. <input type="checkbox"/> |
| 7. | Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture. | 7. <input type="checkbox"/> |
| 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. <input type="checkbox"/> |
| 9. | Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation. | 9. <input type="checkbox"/> |
| 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. <input type="checkbox"/> |
| 11. | Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator). | 11. <input type="checkbox"/> |

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
- 2b. Rest tremor
- 2c. Rigidity
- 2d. Bradykinesia
- 2e. Gait disturbances
- 2f. Other (specify) _____

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
- 97 = Other neurological disorder(s) (specify) _____
- 13 = Normal pressure hydrocephalus
- 15 = Psychogenic illness
- 16 = Vascular parkinsonism
- 17 = No PD nor other neurological disorder
- 18 = Spinocerebellar Ataxia (SCA)

PPMI

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
---	---	---

[¹⁸F] Florbetaben - PPMI ELIGIBILITY

1	2	1
---	---	---

SUBJECT ID	<input style="width: 100%;" type="text"/>	VISIT NO	<input style="width: 100%;" type="text"/>								
INITIALS	<input style="width: 100%;" type="text"/>	SITE NO	<input style="width: 100%;" type="text"/>								
		VISIT DATE	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"><input type="text"/></td> <td style="width: 20px; height: 20px;"><input type="text"/></td> <td style="width: 20px; height: 20px;"><input type="text"/></td> <td style="width: 20px; height: 20px;"><input type="text"/></td> </tr> <tr> <td style="text-align: center; font-size: small;">MM</td> <td style="text-align: center; font-size: small;">DD</td> <td colspan="2" style="text-align: center; font-size: small;">YYYY</td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	MM	DD	YYYY	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>								
MM	DD	YYYY									

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

B. Date informed consent for participation in [¹⁸F] Florbetaben-PPMI companion protocol was signed:

B.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	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 [¹⁸F] 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

[¹⁸F] Florbetaben - PPMI TELEPHONE FOLLOW-UP

1 2 2

SUBJECT ID [][][][]

VISIT NO [F] [L] []

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][] [][]
MM DD

[][] [][]
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. If No (0), please indicate the reason: 1a. []
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
---	---	---

[¹⁸F] 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? 4.
(0 = No, 1 = Yes)

- 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 [¹⁸F] Florbetaben injection? (0 = No, 1 = Yes) 4b.

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

PPMI

1 3 2

[¹⁸F] Florbetaben - PPMI IMAGING

1 2 3

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? 1.
(0 = No, 1 = Yes)

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
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1	3	1
---	---	---

SUBJECT ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT NO	<input type="text"/>	<input type="text"/>	<input type="text"/>							
INITIALS	<input type="text"/>	<input type="text"/>	<input type="text"/>	SITE NO	<input type="text"/>	<input type="text"/>	<input type="text"/>	VISIT DATE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
									MM		DD			YYYY	

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

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 5 4

CONTACT INFORMATION- PPMI PATHOLOGY CORE

1 3 5

SUBJECT ID VISIT NO

INITIALS SITE NO VISIT DATE

MM DD YYYY

1. Did the subject agree to share contact information with the PPMI Pathology Core? 1.
(0 = No, 1 = Yes)

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

1b. Date contact form transmitted to the PPMI Pathology Core: 1b.
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) 1.
(If No, comment below)

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) 4.
(If Yes, comment below) (If complication was an adverse event, please remember to document event on the Adverse Event log.)

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. If No (0), please indicate the reason: 1a.

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
PBMC

1 3 2

1 5 0

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE
MM

DD

YYYY

A. Date of last food intake:

A.
MM

DD

YYYY

B. Time of last intake of food:

B. :
24-hour clock

Ba. Fasting status:

(1 = fasted (minimum of 8 hours), 2 = low fat diet, 3 = not fasted, no low fat diet)

Ba.

1. PBMC sample collected:

(0 = No, 1 = Collected, 2 = Partial Collection, 3 = attempted, no collection)
If response is 0, 2 or 3, specify in comments.

1.

2. Date PBMC sample collected:

2.
MM

DD

YYYY

3. Time PBMC sample collected:

3. :
24-hour clock

4. Volume collected in milliliters:

(If volume is less than expected, specify in comments)

4.

5. Date sample shipped:

5.
MM

DD

YYYY

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.

--

(1 = Initial Consent, 2 = Continued Consent, 3 = Declined Participation,
4 = Withdrew Consent)

1a. If question 1 is 1 or 4, on what date was consent obtained or withdrawn:

1a.

--	--

MM

--	--

DD

--	--	--	--

YYYY

PPMI

COGNITIVE ASSESSMENTS

1 3 2

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 [][] DD [][][][] YYYY

1a. Estimation of surgery date 1a. []
1 = Actual (ACT)
2 = Day Est. (DAY)
3 = Month/Day Est (MD)
4 = Month Est. (MON)

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 (subthalamic 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: _____

PPMI

DETERMINATION OF FALLS

1	3	2
---	---	---

2	0	3
---	---	---

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE

MM DD

YYYY

YYYY

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

1. Does the participant report freezing of gait occurring **in the past week?** 1.

0 = None
 1 = Rare freezing when walking; may have start hesitation
 2 = Occasional freezing when walking
 3 = Frequent freezing; occasional falls from freezing
 4 = Frequent falls from freezing

2. Does the participant report falls occurring **in the past week** that were not related to freezing of gait? 2.

0 = None
 1 = Rare falling
 2 = Occasionally falls, less than once per day
 3 = Falls on average of once daily
 4 = Falls more than once daily

3. Does the participant report freezing of gait occurring **in the past 12 months?** 3.

0 = None
 1 = Rare freezing when walking; may have start hesitation
 2 = Occasional freezing when walking
 3 = Frequent freezing; occasional falls from freezing
 4 = Frequent falls from freezing

4. Does the participant report falls occurring **in the past 12 months** that were not related to freezing of gait? 4.

0 = None
 1 = Rare falling
 2 = Occasionally falls, less than once per day
 3 = Falls on average of once daily
 4 = Falls more than once daily

PPMI

DETERMINATION OF FALLS

1	3	2
---	---	---

2	0	3
---	---	---

SUBJECT ID

--	--	--	--	--

VISIT NO

--	--	--

If participant responded 1-4 to question 4, complete questions 5 and 6.

5. Did any of these falls result in the following injuries?

5a. Fracture of hip or lower limb (0 = No, 1 = Yes) 5a.

5b. Fracture of upper extremity (0 = No, 1 = Yes) 5b.

5c. Skull fracture (0 = No, 1 = Yes) 5c.

5d. Other fracture (0 = No, 1 = Yes)
If yes, please specify _____ 5d.

5e. Head injury without loss of consciousness (0 = No, 1 = Yes) 5e.

5f. Head injury with loss of consciousness (0 = No, 1 = Yes) 5f.

5g. Laceration requiring sutures (stitches) (0 = No, 1 = Yes) 5g.

5h. Other (0 = No, 1 = Yes)
If yes, please specify _____ 5h.

6. Did any of these falls result in:

6a. Outpatient visit to a healthcare provider (0 = No, 1 = Yes) 6a.

6b. Visit to the ER (0 = No, 1 = Yes) 6b.

6c. Hospitalization (0 = No, 1 = Yes) 6c.

6d. Surgery (0 = No, 1 = Yes) 6d.

6e. Institutionalization (0 = No, 1 = Yes) 6e.

PPMI

1 3 2

MODIFIED TELEPHONE FOLLOW-UP

2 0 4

SUBJECT ID [][][][][]

VISIT NO P [][]

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. If No (0), please indicate the reason: 1a. []

- 1 = phone disconnected
- 2 = multiple messages left on answering machine were not returned
- 3 = subject moved - unable to locate
- 5 = other (specify) _____

1b. If Yes (1), is the Subject still alive? (0 = No, 1 = Yes) 1b. []

1b1. If No, indicate date of death: 1b1. [][] MM [][] DD [][][][] YYYY

1b2. Date of death is: 1b2. []
1 = Actual (ACT)
2 = Day Est. (DAY)
3 = Mon/Day Est. (MD)
4 = Month Est. (MON)

1c. Has there been a change in the Subject's contact information? 1c. []
If Yes (1), please document the new contact information in the Subject's study record and Confidential Subject Identification Log.

2. Comments:

PPMI

1 3 2

MODIFIED SEMANTIC FLUENCY

2 0 5

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.

PPMI

1 3 2

MODIFIED COGNITIVE ASSESSMENTS

2 0 6

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. :
- 7. MoCA (24-hour clock) 7. :
- 8. Trail Making A & B (24-hour clock) 8. :
- 9. Boston Naming Test (24-hour clock) 9. :
- 10. Lexical Fluency (24-hour clock) 10. :

Comments:

1 3 2

2 0 8

SUBJECT ID [][][][][][]

VISIT NO [][][]

INITIALS [][][]

SITE NO [][][]

VISIT DATE [][]
MM

[][]
DD

[][][][]
YYYY

Part A:

1. Did the Subject complete the test within 150 seconds (maximum time)? (0 = No, 1 = Yes) 1. []

1a. If Yes (1), time to complete (seconds): 1a. [][][]

1b. If No (0), number correct: 1b. [][][]

Part B:

2. Did the Subject complete the test within 300 seconds (maximum time)? (0 = No, 1 = Yes) 2. []

2a. If Yes (1), time to complete (seconds): 2a. [][][]

2b. If No (0), number correct: 2b. [][][]

PPMI

MODIFIED BOSTON NAMING TEST

1 3 2

2 0 9

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE
MM

DD

YYYY

1. Number of correct responses:

1.

PPMI

LEXICAL FLUENCY

1	3	2
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2	1	0
---	---	---

SUBJECT ID

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VISIT NO

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INITIALS

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SITE NO

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VISIT DATE

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MM

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DD

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YYYY

1. Record the number of words that begin with **F** named in one minute (60 seconds):

--	--

2. Record the number of words that begin with **A** named in one minute (60 seconds):

--	--

3. Record the number of words that begin with **S** named in one minute (60 seconds):

--	--

PPMI

1 3 2

PARTICIPANT QUESTIONNAIRE

2 1 1

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE
 MM

DD

YYYY

A. Who completed this questionnaire? (1 = participant, 2 = caregiver)

A.

When answering these questions, please think about the last week.

- | | | | | |
|-----|---|------|-------|-------------|
| 1. | Do you have trouble rising from a chair? | 0=No | 1=Yes | 2=Uncertain |
| 2. | Is your handwriting smaller than it once was? | 0=No | 1=Yes | 2=Uncertain |
| 3. | Do people tell you that your voice is softer than it once was? | 0=No | 1=Yes | 2=Uncertain |
| 4. | Is your balance poor? | 0=No | 1=Yes | 2=Uncertain |
| 5. | Do your feet ever seem to get stuck to the floor? | 0=No | 1=Yes | 2=Uncertain |
| 6. | Do people tell you that your face seems less expressive than it once did? | 0=No | 1=Yes | 2=Uncertain |
| 7. | Do your arms or legs shake? | 0=No | 1=Yes | 2=Uncertain |
| 8. | Do you have trouble buttoning buttons? | 0=No | 1=Yes | 2=Uncertain |
| 9. | Do you shuffle your feet and/or take tiny steps when you walk? | 0=No | 1=Yes | 2=Uncertain |
| 10. | Do you move more slowly than other people your age? | 0=No | 1=Yes | 2=Uncertain |
| 11. | Has anyone ever told you that you have Parkinson's disease? | 0=No | 1=Yes | 2=Uncertain |

PPMI

1 3 2

SUBJECT CONTINUATION PRODROMAL

2 1 2

SUBJECT ID

VISIT NO V 1 0

INITIALS

SITE NO

VISIT DATE
MM

DD

YYYY

1. Did subject agree to continue in PPMI beyond Visit 10 / Month 48?
(0 = No, 1 = Yes)

A.

3. Date informed consent signed to continue
post Visit 10 / Month 48:

3.
MM

DD

YYYY

PPMI

1 3 2

SUBJECT CONTINUATION ONTO MODIFIED SOA (PD&HC)

2 1 3

SUBJECT ID VISIT NO
INITIALS SITE NO VISIT DATE
MM DD YYYY

1. Did subject agree to continue in PPMI beyond January 01, 2019 using modified SOA? (0 = No, 1 = Yes) 1.

2. Last visit completed prior to January 01, 2019: 2.

3. Date informed consent signed to continue post January 01, 2019: 3.
MM DD YYYY