PPMI

Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a lumbar puncture, skin biopsy, and/or dopamine imaging procedure to assess for adverse events. In the event lumbar puncture, skin biopsy, and/or dopamine imaging are performed across multiple dates, complete a separate form for each assessment date.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Please indicate which of the procedure(s) were performed on this assessment date:
   - ❒ LP
   - ❒ Skin biopsy
   - ❒ Dopamine Imaging Scan

   1a. Were adverse events assessed following the procedure(s) on this assessment date?
   - ○ No
   - ○ Yes

   i. If No, please explain:

   _____

   _____

   _____

   ii. If Yes, were any adverse events observed?
   - ○ No
   - ○ Yes

If question 1.a.ii is "Yes", document information on the Adverse Event Log.

PPMI

Adverse Event Log

Instructions: Assess for adverse events (observed, elicited from, or volunteered by the participant) at visits when dopamine imaging, lumbar puncture, or skin biopsy are conducted, as well as by telephone 2-3 days later and followed to resolution or appropriate outcome (not more than 30 days post-procedure). Enter each change in "severity" on a new row. Please specify start and stop dates as actual or estimated (representing your best reasonable estimate). If recording a serious adverse event, please refer to the Operations Manual for reporting guidance.

A. Site Aware Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Adverse Event: _____
2. Start Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
3. Stop Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
4. Severity:

   ○ Mild ○ Moderate ○ Severe
5. Serious:

   ○ No ○ Yes
6. Relationship to Study:

   ○ Unrelated

   ○ Unlikely

   ○ Possible

   ○ Probable

   ○ Definite
7. What procedure is this related to:

   ☑ ☐

8. Resulted in premature withdrawal from study:

   ○ No ○ Yes

   Complete when resolved (or up to 30 days post-procedure):

9. Primary Outcome:

   ○ Recovered

   ○ Under treatment / observation

   ○ Change in AE characteristic

   ○ Sequelae

   ○ Fatal

   ○ Unknown

PPMI

Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following a lumbar puncture, skin biopsy, or dopamine imaging procedure to assess for adverse events.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was an LP, skin biopsy or dopamine imaging scan conducted at this visit?
   - ○ No
   - ○ Yes

2. Was contact made during this telephone call?
   - ○ No
   - ○ Yes

   2a. If no, indicate the reason:
   - ○ Phone disconnected/number no longer in service
   - ○ Messages for participant were not returned
   - ○ Participant moved/unable to locate
   - ○ Other, specify: _____

Please also use this time to check whether the participant has signed up for myPPMI and encourage them to do so.

3. Were any adverse events reported by the participant?
   - ○ No
   - ○ Yes

If question 3 is "Yes", new adverse event(s) should be documented on the Adverse Event Log.

PPMI

Baseline Visit Start

The information below is collected to assist in participant enrollment status metrics.

A. Date Baseline visit started: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Benton Judgment of Line Orientation

BL	MTH 12 V04	MTH 24 V06	MTH 36 V08	MTH 48 V10	MTH 60 V12	MTH 72 V13	MTH 84 V14	MTH 96 V15	MTH 108 V16	MTH 120 V17	MTH 132 V18	MTH 144 V19	MTH 156 V20
Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)	Form H (Odd)	Form H (Even)

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Version Used: ○ Odd ○ Even

Item	Answer		Item	Answer	
1. Item 1	○ Incorrect	○ Correct	2. Item 2	○ Incorrect	○ Correct
3. Item 3	○ Incorrect	○ Correct	4. Item 4	○ Incorrect	○ Correct
5. Item 5	○ Incorrect	○ Correct	6. Item 6	○ Incorrect	○ Correct
7. Item 7	○ Incorrect	○ Correct	8. Item 8	○ Incorrect	○ Correct
9. Item 9	○ Incorrect	○ Correct	10. Item 10	○ Incorrect	○ Correct
11. Item 11	○ Incorrect	○ Correct	12. Item 12	○ Incorrect	○ Correct
13. Item 13	○ Incorrect	○ Correct	14. Item 14	○ Incorrect	○ Correct
15. Item 15	○ Incorrect	○ Correct	16. Item 16	○ Incorrect	○ Correct
17. Item 17	○ Incorrect	○ Correct	18. Item 18	○ Incorrect	○ Correct
19. Item 19	○ Incorrect	○ Correct	20. Item 20	○ Incorrect	○ Correct
21. Item 21	○ Incorrect	○ Correct	22. Item 22	○ Incorrect	○ Correct
23. Item 23	○ Incorrect	○ Correct	24. Item 24	○ Incorrect	○ Correct
25. Item 25	○ Incorrect	○ Correct	26. Item 26	○ Incorrect	○ Correct
27. Item 27	○ Incorrect	○ Correct	28. Item 28	○ Incorrect	○ Correct
29. Item 29	○ Incorrect	○ Correct	30. Item 30	○ Incorrect	○ Correct

PPMI

Clinical Diagnosis

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Instructions: Please select ONE answer below based on the Investigator's assessment of the clinical diagnosis of this participant.

The clinical diagnosis may reflect either the diagnosis provided by the participant's clinician/neurologist and/or the clinical judgment of the Investigator.

1. Most likely clinical diagnosis:
   - ○ Idiopathic PD
   - ○ Alzheimer's disease
   - ○ Frontotemporal dementia
   - ○ Corticobasal syndrome
   - ○ Dementia with Lewy bodies
   - ○ Dopa-responsive dystonia
   - ○ Essential tremor
   - ○ Hemiparkinson/hemiatrophy syndrome
   - ○ Juvenile autosomal recessive parkinsonism
   - ○ Motor neuron disease with parkinsonism
   - ○ Multiple system atrophy
   - ○ Neuroleptic-induced parkinsonism
   - ○ Normal pressure hydrocephalus
   - ○ Progressive supranuclear palsy
   - ○ Psychogenic parkinsonism
   - ○ Vascular parkinsonism
   - ○ No PD nor other neurological disorder
   - ○ Spinocerebellar Ataxia (SCA)
   - ○ Prodromal Synucleinopathy (e.g., RBD)
   - ○ Other neurological disorder(s),specify: _____

2. Indicate if the diagnosis occurred between the last study visit and this study visit:
   - ○ No
   - ○ Yes

2a. Indicate date of diagnosis (estimated date is acceptable): __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

If diagnosis changed since last visit, complete the following question:

3. The clinical diagnosis changed since the last visit. Please enter rationale to explain this new diagnosis:

_____

_____

_____

_____

PPMI

Clinical Global Impression (CGI) - Investigator

Instructions: Assess the level of the participant's overall Parkinson's type motor and non-motor signs/symptoms broadly* during the past 4 weeks. Consider both the history provided and your in-person examination.

*Consider motor signs/symptoms (e.g., tremor, rigidity, bradykinesia, gait/balance, and dyskinesias/fluctuations) and non-motor signs/symptoms (e.g., cognition, depression, anxiety, psychosis, impulse control disorders, sleep and wakefulness, fatigue, smell and taste, and autonomic function).

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Investigator Assessment

Score	Overall signs & symptoms score
○ 0	Not assessed
○ 1	Normal (no signs or symptoms)
○ 2	Borderline
○ 3	Mild
○ 4	Moderate
○ 5	Marked
○ 6	Severe
○ 7	Very severe

PPMI

Clinical Labs

1. Blood for clinical labs:

   ○ Collected ○ Not Collected

   i. Date of Collection: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   ii. If not collected, provide reason:

   _____

   _____

   _____

2. Blood for coagulation panel (PT/PTT):

   ○ Collected ○ Not Collected

   i. Date of Collection: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   ii. If not collected, provide reason:

   _____

   _____

   _____

PPMI

Clock Drawing

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Time

1. One hand points to "2" (Roman numerals also count).

   ○ 0 ○ 1

2. Exactly two hands.

   ○ 0 ○ 1

3. Absence of intrusive marks (e.g., writing or hands indicating incorrect time, hand points to number 10, tic marks, time written in text [11:10, 10 after 11]).

   ○ 0 ○ 1

Numbers

4. Numbers are inside the clock circle (may touch perimeter, but may not extend outside of circle).

   ○ 0 ○ 1

5. All numbers 1-12 are present, no duplicates or omissions.

   ○ 0 ○ 1

Spacing

6. Numbers are spaced equally or nearly equally from each other.

   ○ 0 ○ 1

7. Numbers spaced equally or nearly equally from the edge of the circle.

   ○ 0 ○ 1

PPMI

Cognitive Categorization

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Indicate the source of information:

○ Participant ○ Caregiver ○ Participant and Caregiver

Determining Report of Cognitive Decline

Based on information provided by the participant, the caregiver/informant, and/or based on the Site Investigator's judgment, determine whether the participant has experienced a decline in cognitive abilities compared with his/her usual abilities during adulthood. 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 participant experienced cognitive decline?

○ No ○ Yes

Determining Functional Impairment

Based on information provided by the participant, the caregiver/informant, and/or based on the Site Investigator's judgment, determine whether the participant 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?

○ No ○ Yes

Determining Cognitive Diagnosis

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

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

   ○ Normal Cognition

   ○ Mild Cognitive Impairment (MCI)

   ○ Dementia

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

   ○ 90 - 100%

   ○ 50 - 89%

   ○ 10 - 49%

   ○ 0 - 9%

5. Did you review any neuropsychological tests (including MoCA scores) in making this determination?

   ○ No ○ Yes

PPMI

Cognitive Change

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Have you noticed that you are having more problems with thinking, such as difficulty with memory or concentration, that is a change from your normal abilities?

   Some examples of thinking problems might include:

   - Memory: such as remembering what someone recently told you, familiar names, or upcoming events.
   - Concentration: such as reading an article or book, or watching a television show or movie.
   - Organization: such as paying bills, managing medications, or organizing and completing a shopping list.
   - Spatial ability: such as driving or finding one's way around an unfamiliar location.
   - Understanding language: such as making sense of conversations or finding words when talking.

   ○ No ○ Yes

PPMI

Conclusion of Study Participation

The *Conclusion of Study Participation* form should be completed when a participant either completes study participation, decides to no longer participate in the study/withdraws consent, or dies.

When applicable, the date of conclusion of participation would be the date of death. See Assessments Manual for more detail.

1. Date of conclusion of participation: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

2. Please select reason(s) for conclusion of study participation (select all that apply):
   - ❒ Adverse Event
   - ❒ Completed Study per protocol
   - ❒ Death
   - ❒ Family, care-partner, or social issues (such as work/job obligations)
   - ❒ Lost to follow up
   - ❒ Non-compliance with study procedures
   - ❒ Transportation/Travel issues (ex: logistics or travel, moved away from study site)
   - ❒ Burden of study procedures (other than travel)
   - ❒ Decline in health
     - i. Was this due to increasing PD disability? ○ Yes ○ No ○ Unknown
   - ❒ Site closure
   - ❒ General disinterest
   - ❒ Other, please specify:

     _____

     _____

     _____

     _____

PPMI

Concomitant Medication Log

If the exact start date or stop date is unknown, please select the first of the month in the applicable month and year.

1. Medication Name (Generic preferred): _____
2. Indication: ☐
   Specify Other Indication: _____
3. Start Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
4. Stop Date (If applicable): __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Continuing Consent

Discussion of continued consent in PPMI ensures that the participant and/or their research proxy still understands the voluntary nature of participation, has the opportunity to ask questions or express concerns, may withdraw consent given previously, or may designate any changes to optional PPMI activity participation.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Participant (or research proxy) confirmed willingness to continued participation in PPMI Clinical?

   ○ No ○ Yes

   If no, include comment and complete Conclusion of Participation form:

   _____

   _____

   _____

   _____

2. Have there been any changes to the participant (or research proxy) willingness to participate in any of the PPMI Clinical optional activities (e.g., sharing of contact info, future contact by study team)?

   ○ No ○ Yes

   If yes, update the Informed Consent Tracking Log.

PPMI

CT Scan

1. Was a CT scan completed as part of the PPMI study to assess safety for screening Lumbar Puncture?

   ○ Completed

   ○ Not Completed

   1a. If completed, provide date of scan:

   __ __/__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Demographics

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Date of Birth: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
2. Sex of Participant at birth:

   ○ Male ○ Female
3. Of childbearing potential:

   ○ Yes ○ No
4. How do you live your life day to day?

   ○ Woman (or trans woman)

   ○ Man (or trans man)

   ○ Non-binary

   ○ Another term, specify: _____
5. Which of the following best represents how you think of yourself? (Check all that apply)

   ❒ Gay/Lesbian

   ❒ Straight/Heterosexual

   ❒ Bisexual

   ❒ Pansexual

   ❒ Asexual

   ❒ Other: _____
6. Handedness:

   ○ Right ○ Left ○ Mixed
7. **Ethnicity** – Indicate the ethnicity with which the participant most closely identifies (required):

   ○ Hispanic or Latino (Spanish origin)

   ○ Not Hispanic or Latino (Spanish origin)

   ○ Unknown or not reported

   Descent – Indicate whether the participant most closely identifies with any of the following descents (required):
8. Does participant identify as being of Ashkenazi Jewish descent?

   ○ Yes ○ No ○ Unknown or not reported
9. Does participant identify as being of Basque descent?

   ○ Yes ○ No ○ Unknown or not reported
10. Does participant identify as being of African Berber descent?

    ○ Yes ○ No ○ Unknown or not reported

11. **Race** – Indicate the race(s) with which the participant most closely identifies (required – check all that apply):

    ❒ American Indian or Alaska Native

    ❒ White/Caucasian

    ❒ Black or African American

    ❒ Native Hawaiian or Other Pacific Islander

    ❒ Asian

    ❒ Unknown or not reported

    ❒ Other, please specify: _____

PPMI

Determination of Freezing and Falls

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Indicate the source of information:

○ Participant ○ Caregiver ○ Participant and Caregiver

1. Does the participant currently experience freezing of gait?

   ○ 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 currently experience falls not related to freezing of gait?

   ○ 0 = None

   ○ 1 = Rare falling

   ○ 2 = Occasionally falls, less than once per day

   ○ 3 = Falls an average of once daily

   ○ 4 = Falls more than once daily

3. In the past 12 months, has the participant experienced freezing of gait?

   ○ 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. In the past 12 months, has the participant experienced falls that were not related to freezing of gait?

   ○ 0 = None

   ○ 1 = Rare falling

   ○ 2 = Occasionally falls, less than once per day

   ○ 3 = Falls an average of once daily

   ○ 4 = Falls more than once daily

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

5a. Fracture of the hip or lower limb	○ No	○ Yes
5b. Fracture of upper extremity	○ No	○ Yes
5c. Skull fracture	○ No	○ Yes
5d. Other fracture	○ No	○ Yes
If yes, please specify: _____		
5e. Head injury without loss of consciousness	○ No	○ Yes
5f. Head injury with loss of consciousness	○ No	○ Yes
5g. Laceration requiring sutures (stitches)	○ No	○ Yes
5h. Other injury	○ No	○ Yes
If yes, please specify: _____		

6. Did any of these falls result in:

6a. Outpatient visit to a healthcare provider (Including urgent care facility)	○ No	○ Yes
6b. Visit to the ER	○ No	○ Yes
6c. Hospitalization	○ No	○ Yes
6d. Surgery	○ No	○ Yes
6e. Institutionalization	○ No	○ Yes

PPMI

Documentation of Informed Consent

Form instructions: Document date participant signed consent as the "Assessment Date" below.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Informed consent was discussed with participant and/or legally authorized representative for the PPMI 002 Clinical Study. Participant and/or legally authorized representative was given adequate time to read the informed consent, the opportunity to ask questions and consent was obtained prior to any study procedures being performed.

   ○ No ○ Yes

Monitor responsibilities

- Verify site process for obtaining informed consent is adequate according to 21 CFR 56.109(c) and 28 (21 CFR 50.27).
- Current approved ICF(s) version(s) are signed.
- Informed consent was obtained by person authorized on site delegation log.

PPMI

Dopamine Imaging

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

If using a previously acquired dopamine imaging scan, record the Assessment Date as the date of this visit.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Dopamine imaging scan:

   ○ Not Completed

   ○ Completed at this visit

   ○ Completed using a previously acquired dopamine imaging scan (i.e., acquired prior to participant's consent to PPMI)

   1a. If using a previously acquired dopamine imaging scan, provide date of scan:

   __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   1b. If not completed, provide reason:

   _____

   _____

   _____

   _____

2. Indicate tracer used: ☑ [ ]

3. Imaging Site:

   ❒ Completed at another PPMI site on behalf of this clinical site

PPMI

Eligibility Override

A. Date of Eligibility Override: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Epworth Sleepiness Scale

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Source of Information:

○ Participant ○ Caregiver ○ Participant and Caregiver

How likely are you to doze off or fall asleep in the 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:

   ○ 0 = Would never doze

   ○ 1 = Slight chance of dozing

   ○ 2 = Moderate Chance of Dozing

   ○ 3 = High chance of dozing

2. Watching TV:

   ○ 0 = Would never doze

   ○ 1 = Slight chance of dozing

   ○ 2 = Moderate Chance of Dozing

   ○ 3 = High chance of dozing

3. Sitting, inactive in a public place (e.g., a theater or a meeting):

   ○ 0 = Would never doze

   ○ 1 = Slight chance of dozing

   ○ 2 = Moderate Chance of Dozing

   ○ 3 = High chance of dozing

4. As a passenger in a car for an hour without a break:
   - ○ 0 = Would never doze
   - ○ 1 = Slight chance of dozing
   - ○ 2 = Moderate Chance of Dozing
   - ○ 3 = High chance of dozing
5. Lying down to rest in the afternoon when circumstances permit:
   - ○ 0 = Would never doze
   - ○ 1 = Slight chance of dozing
   - ○ 2 = Moderate Chance of Dozing
   - ○ 3 = High chance of dozing
6. Sitting and talking to someone:
   - ○ 0 = Would never doze
   - ○ 1 = Slight chance of dozing
   - ○ 2 = Moderate Chance of Dozing
   - ○ 3 = High chance of dozing
7. Sitting quietly after a lunch without alcohol:
   - ○ 0 = Would never doze
   - ○ 1 = Slight chance of dozing
   - ○ 2 = Moderate Chance of Dozing
   - ○ 3 = High chance of dozing
8. In a car, while stopped for a few minutes in traffic:
   - ○ 0 = Would never doze
   - ○ 1 = Slight chance of dozing
   - ○ 2 = Moderate Chance of Dozing
   - ○ 3 = High chance of dozing

PPMI

Family History

Form Instructions:

Completion of the following questions will capture people in your family with and without Parkinson's disease or Parkinsonism. Please indicate the number of relatives (living or deceased) for each family type listed below and the number of these relatives who have or had PD or Parkinsonism.

For example, if you have two maternal aunts and one has PD, enter "2" in the Number of Family Members box and enter "1" in the Number with PD or Parkinsonism box. If you have 2 full brothers and 2 full sisters and none have PD or Parkinsonism, enter "2" in the Number of Family Members box for each family type and "0" in the Number with PD or Parkinsonism box. If you are unsure if the listed relative had PD or Parkinsonism, please add a "0" to the Number with PD box.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Do you have any **known** family history of Parkinson's Disease or Parkinsonism?

○ No ○ Yes

Relative	I. Number of Family Members	II. Number with PD or Parkinsonism
a. Full Brothers	_____	_____
b. Full Sisters	_____	_____
c. Maternal Half Siblings	_____	_____
d. Paternal Half Siblings	_____	_____
e. Maternal Aunts and Uncles	_____	_____
f. Paternal Aunts and Uncles	_____	_____
g. Maternal Cousins	_____	_____
h. Paternal Cousins	_____	_____
i. Children	_____	_____

III. Do any of these family members have PD or Parkinsonism?

j.	Biological Mother	○ No	○ Yes
k.	Biological Father	○ No	○ Yes
l.	Maternal Grandmother	○ No	○ Yes
m.	Maternal Grandfather	○ No	○ Yes
n.	Paternal Grandmother	○ No	○ Yes
o.	Paternal Grandfather	○ No	○ Yes

2. Do you have a more distant relative not listed above who has/had Parkinson's disease or Parkinsonism?

○ No ○ Yes

PPMI

Features of Parkinsonism

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. **Bradykinesia:** Defined as slowness of movement AND decrement in amplitude or speed or progressive hesitations / halts as movements are continued.

   Bradykinesia is present and typical for parkinsonism:

   ○ No ○ Yes ○ Uncertain

2. **Rigidity:** Judged on slow passive movement of major joints with the patient in a relaxed position. Rigidity refers to "lead-pipe" resistance that is velocity-independent resistance to passive movement not solely reflecting failure to relax. Isolated cogwheeling without lead-pipe rigidity does not fulfill minimum requirements for rigidity.

   Rigidity is present and typical for parkinsonism:

   ○ No ○ Yes ○ Uncertain

3. **Rest tremor:** Rest tremor refers to 4-6 Hz tremor in the fully resting limb which is suppressed during movement initiation. Kinetic and postural tremor do not qualify for parkinsonism criteria.

   Rest tremor is present and typical for parkinsonism:

   ○ No ○ Yes ○ Uncertain

4. **Postural or gait disturbance:** Postural instability not caused by primary visual, vestibular, cerebellar or proprioceptive dysfunction.

   Postural disturbance is present and typical for parkinsonism:

   ○ No ○ Yes ○ Uncertain

5. To what degree are you confident that this participant has abnormalities consistent with a neurodegenerative parkinsonian syndrome (PS)?

   ○ Abnormalities that are signs of PS (90 - 100%)

   ○ Abnormalities that are likely signs of PS (70 - 89%)

   ○ Abnormalities that may be signs of PS (50 - 69%)

   ○ Non-specific abnormalities (25 - 49%)

   ○ No evidence of parkinsonian signs (0 - 24%)

PPMI

Features of REM Behavior Disorder

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Does the participant have a clinical diagnosis of RBD?

   ○ No

   ○ Yes

   a. Indicate date of RBD symptom onset: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   b. Indicate date of clinical diagnosis: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   c. Does the participant have a polysomnography (PSG) consistent with diagnosis of RBD?

      ○ No

      ○ Yes

      i. Indicate date of PSG: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

      ii. Was this PSG reported by the participant or confirmed by the clinical site?

         ○ Participant-reported

         ○ Site-confirmed

PPMI

General Physical Exam

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

<u>Organ System Abnormalities by Examination (Other than PD):</u>

1. Skin:

   ○ Normal ○ Abnormal ○ Cannot Assess

   If abnormal, describe briefly:

   _____

   _____

2. Head/Neck/Lymphatic:

   ○ Normal ○ Abnormal ○ Cannot Assess

   If abnormal, describe briefly:

   _____

   _____

3. Eyes:

   ○ Normal ○ Abnormal ○ Cannot Assess

   If abnormal, describe briefly:

   _____

   _____

4. Ears/Nose/Throat:

   ○ Normal ○ Abnormal ○ Cannot Assess

   If abnormal, describe briefly:

   _____

   _____

5. Lungs:

○ Normal ○ Abnormal ○ Cannot Assess

If abnormal, describe briefly:

_____

_____

6. Cardiovascular (including peripheral vascular):

○ Normal ○ Abnormal ○ Cannot Assess

If abnormal, describe briefly:

_____

_____

7. Abdomen:

○ Normal ○ Abnormal ○ Cannot Assess

If abnormal, describe briefly:

_____

_____

8. Musculoskeletal:

○ Normal ○ Abnormal ○ Cannot Assess

If abnormal, describe briefly:

_____

_____

9. Neurological (not including PD, if applicable):

○ Normal ○ Abnormal ○ Cannot Assess

If abnormal, describe briefly:

_____

_____

10. Psychiatric:

    ○ Normal ○ Abnormal ○ Cannot Assess

    If abnormal, describe briefly:

    _____

    _____

11. Other:

    ○ Normal ○ Abnormal ○ Cannot Assess

    Specify location and describe:

    _____

    _____

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Geriatric Depression Scale (Short Version)

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Form Instructions: Choose the best answer for how you have felt over the **past week**.

1. Are you basically satisfied with your life?	○ No	○ Yes
2. Have you dropped many of your activities and interests?	○ No	○ Yes
3. Do you feel that your life is empty?	○ No	○ Yes
4. Do you often get bored?	○ No	○ Yes
5. Are you in good spirits most of the time?	○ No	○ Yes
6. Are you afraid that something bad is going to happen to you?	○ No	○ Yes
7. Do you feel happy most of the time?	○ No	○ Yes
8. Do you often feel helpless?	○ No	○ Yes
9. Do you prefer to stay at home, rather than going out and doing new things?	○ No	○ Yes
10. Do you feel you have more problems with memory than most?	○ No	○ Yes
11. Do you think it is wonderful to be alive now?	○ No	○ Yes
12. Do you feel pretty worthless the way you are now?	○ No	○ Yes
13. Do you feel full of energy?	○ No	○ Yes
14. Do you feel that your situation is hopeless?	○ No	○ Yes
15. Do you think that most people are better off than you are?	○ No	○ Yes

Sheikh JI, Yesavage JA: Geriatric Depression Scale (GDS): Recent evidence and development of a shorter version. Clinical Gerontology: A Guide to Assessment and Intervention. 165-173, NY: The Haworth Press, 1986.

PPMI

Healthy Control Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria:

1. Male or Female age 30 years or older at Screening visit.

   ○ Yes ○ No

2. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

3. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

4. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

6. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of Baseline SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

Exclusion Criteria:

1. First degree relative with PD (i.e., biologic parent, sibling, child).

   ○ No ○ Yes

2. Current or active clinically significant neurological disorder (in the opinion of the Investigator).

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

PPMI

Hopkins Verbal Learning Test - Revised

BL	MTH 12 V04	MTH 24 V06	MTH 36 V08	MTH 48 V10	MTH 60 V12	MTH 72 V13	MTH 84 V14	MTH 96 V15	MTH 108 V16	MTH 120 V17	MTH 132 V18	MTH 144 V19	MTH 156 V20
Form 1	Form 2	Form 3	Form 4	Form 5	Form 6	Form 1	Form 2	Form 3	Form 4	Form 5	Form 6	Form 1	Form 2

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Indicate the form version used at this visit:

○ Form 1

○ Form 2

○ Form 3

○ Form 4

○ Form 5

○ Form 6

If form used is different than indicated in the protocol, comment below:

_____

_____

1. Immediate Recall:

a. Number Correct - Trial 1: _____

b. Number Correct - Trial 2: _____

c. Number Correct - Trial 3: _____

2. Delayed Recall:

a. Number Correct - Trial 4: _____

3. Delayed Recognition:

a. Total Number of true positives ("hits"): _____

b. Total Number of false positives, related: _____

c. Total Number of false positives, unrelated: _____

PPMI

IDEA Cognitive Screen

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. I will tell you the name of something and I want you to describe what it is.

   What is a bridge?

   ○ 0 = Incorrect

   ○ 2 = Correct

2. I want you to name as many different animals as you can in one (1) minute.

   Number of animals named:

   ○ 0 = 0-3 animals named

   ○ 1 = 4-7 animals named

   ○ 2 = 8 or more animals named

3. Who is the Chief/Head/Leader of this village?

   ○ 0 = Incorrect

   ○ 1 = Correct

4. What day of the week is it?

   ○ 0 = Incorrect

   ○ 2 = Correct

5. Can you tell me the ten (10) words we learned earlier? Try to remember as many as you can.

   ○ 1 = 1 word

   ○ 2 = 2 words

   ○ 3 = 3 words

   ○ 4 = 4 words

   ○ 5 = 5 or more words

6. Can you make the design shown using the 4 matchsticks provided?
   - ❒ 0 = No part of the design was performed correctly
   - ❒ 1 = Middle two matchstick heads pointing same way
   - ❒ 1 = Outside two matchsticks pointing at an angle
   - ❒ 1 = Matchstick heads are orientated correctly

7. Total Score: _____ / 15

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Informed Consent Tracking Log

1. Study Template Version Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
2. Site Version Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
3. Site IRB Approval Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
4. Date ICF Signed: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
5. Select Consent Signed: ☑
6. Reason for Consent:

   ○ Initial Consent ○ Re-consent ○ Transfer from another site ○ LAR/Research Proxy consented

   If Re-consent, explain:

   _____

   _____

   _____

7. Consent to share contact info with FOUND:

   ○ No ○ Yes ○ Not Applicable

8. Consent to share contact info with Pathology Core:

   ○ No ○ Yes ○ Not Applicable

9. Consent to future contact:

   ○ No ○ Yes

PPMI

Initiation of Dopaminergic Therapy

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Has dopaminergic therapy (i.e., levodopa or a dopamine agonist) been initiated (i.e., started) for this participant?

   ○ No ○ Yes

   If yes, record the start date and additional medication information on the LEDD Concomitant Medication Log.

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LEDD Concomitant Medication Log

If the exact start date or stop date is unknown, please select the first of the month in the applicable month and year. If the month is unknown, please enter July 1st in the applicable year.

If the dose of a medication changes (strength, quantity, or frequency), enter a stop date for the previous dose and create a new log entry with the starting date for the new dose. Do not update an existing entry for a change in medication dose.

1. Medication Name (generic preferred): ☑ _____
2. Total Daily Dose Administered (if Liquid, Infusion, or Injection): _____ mg
3. Dose Strength: ☑ _____
4. Dose Taken (1 tab, 2 tab, etc.): _____ capsules or tablets
5. Dose Frequency per Day (numeric only - do not use TID, etc.): _____ times per day
6. Start Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
7. Stop Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Letter-Number Sequencing

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

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

7a.	5 - H - 9 - S - 2 - N - 6 - A (2 - 5 - 6 - 9 - A - H - N - S)	○ 0	○ 1
7b.	D - 1 - R - 9 - B - 4 - K - 3 (1 - 3 - 4 - 9 - B - D - K - R)	○ 0	○ 1
7c.	7 - M - 2 - T - 6 - F - 1 - Z (1 - 2 - 6 - 7 - F- M - T - Z)	○ 0	○ 1

PPMI

Lexical Fluency

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

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

Lumbar Puncture

Note: Indicate date of CSF collection as the "Assessment Date" below.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was the lumbar puncture for collection of CSF completed?

   ○ Not Done

   ○ Collected

   ○ Partial Collection

   ○ Attempted, no collection

   a. Specimen Collection Kit Number: __ __ __ __ __ __

2. Indicate primary reason for issues with CSF collection:

   ○ Participant refused

   ○ Participant not feeling well enough to attempt

   ○ Site issues (e.g., scheduling difficulties on site end)

   ○ History of difficulty obtaining LP (e.g., participant unable to tolerate procedure in the past; adverse events associated with prior lumbar punctures)

   ○ Spinal issues (e.g., recent back surgery, spinal stenosis, etc.)

   ○ Medical contraindications to lumbar puncture (e.g., started anticoagulants, lab results, altered mentation, focal neurologic signs, papilledema, seizures, tumor)

   ○ Other, specify: _____

3. Date of last intake of food: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
4. Time of last intake of food: __ __:__ __ (24-hour clock)
5. Fasting Status:

   ○ Fasted (minimum of 8 hours)

   ○ Low-Fat Diet

   ○ Not Fasted, No Low Fat Diet

6. Is the participant on medication for treating the symptoms of Parkinson's disease?

   ○ No

   ○ Yes

   a. Date of most recent PD medication dosing: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   b. Time of most recent/in-clinic PD medication dosing: __ __:__ __ (24-hour clock)

7. Indicate needle used to collect CSF:
   - ○ 20g Quincke (sharp bevelled) needle
   - ○ 22g Quincke (sharp bevelled) needle
   - ○ 25g Quincke (sharp bevelled) needle
   - ○ 22g Sprotte (atraumatic) needle
   - ○ 24g Sprotte (atraumatic) needle (preferred)
   - ○ 18g
   - ○ Other, specify: _____
8. Indicate method used to collect CSF:
   - ○ Gravity
   - ○ Syringe suction
9. Indicate location where LP performed:
   - ○ L2-L3 Interspace
   - ○ L3-L4 Interspace
   - ○ L4-L5 Interspace
   - ○ L5-S1 Interspace
   - ○ Unknown
10. Position of participant when lumbar puncture performed:
    - ○ Sitting, leaned over (preferred)
    - ○ Lying, curled up on side
    - ○ Prone
    - ○ Unknown
    - ○ Other, specify: _____

11. Time CSF collection completed: __ __:__ __ (24-hour clock)
12. Volume of CSF collected prior to spinning: _____ milliliters
13. Time CSF was centrifuged: __ __:__ __ (24-hour clock)
    (Within 15 minutes from sample collection)
14. Rate of centrifugation for the CSF sample: _____ xg
    a. Duration of centrifugation: _____ minutes
15. Temperature at which CSF tube was spun: _____ ˚C
16. Time CSF sample aliquotted: __ __:__ __ (24-hour clock)
17. Total volume of CSF aliquotted after spinning: _____ milliliters
18. Total number of aliquot tubes: _____

19. Was part of sample discarded due to a bloody tap?
    - ○ No
    - ○ Yes
20. Indicate how samples stored:
    - ○ Freezer
    - ○ Placed on dry ice
    - a. Storage temperature if placed in freezer: _____ ˚C
21. Time samples were either placed in freezer or placed on dryice: __ __:__ __ (24-hour clock)

22. Was part of the sample sent to local lab for analyses?
    - ○ No
    - ○ Yes
    - ○ Site exemption

    If No, specify: _____

23. Was a fluoroscopy performed?
    - ○ No
    - ○ Yes
24. Was a lumbar spine film performed?
    - ○ No
    - ○ Yes
25. Indicate reason for use of additional guidance:
    - ○ Previously failed attempt
    - ○ Uncertain about location
    - ○ Part of standard procedure
    - ○ Other

PPMI

Magnetic Resonance Imaging (MRI)

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. MRI scan:

   ○ Completed

   ○ Not Completed

   If MRI not completed, provide reason:

   _____

   _____

   _____

   _____

2. Is participant on dopaminergic medication (Levodopa formulations or dopamine agonists) for treating the symptoms of Parkinson disease?

   ○ No

   ○ Yes

   2a. Date of last dose prior to scan: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   2b. Time of last dose prior to scan: __ __:__ __ (24-hour clock)

PPMI

MDS UPDRS Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL)

Form Instructions:

MDS-UPDRS Instructions

The MDS-UPDRS has four parts: Part I (non-motor experiences of daily living), Part II (motor experiences of daily living), Part III (motor examination) and Part IV (motor complications). Part I has two components: IA concerns a number of behaviors that are assessed by the investigator with all pertinent information from patients and caregivers, and IB is completed by the patient with or without the aid of the caregiver, but independently of the investigator. These sections can, however, be reviewed by the rater to ensure that all questions are answered clearly and the rater can help explain any perceived ambiguities. Part II is designed to be a self-administered questionnaire like Part IB, but can be reviewed by the investigator to ensure completeness and clarity. Of note, the official versions of Part IA, Part IB and Part II of the MDS-UPDRS do not have separate “ON” or “OFF” ratings. However, for individual programs or protocols the same questions can be used separately for “ON” and “OFF”. Part III has instructions for the rater to give or demonstrate to the patient; it is completed by the rater. Part IV has instructions for the rater and also instructions to be read to the patient. This part integrates patient-derived information with the rater’s clinical observations and judgments and is completed by the rater.

MDS-UPDRS Part I Instructions

Overview: This portion of the scale assesses the non-motor impact of Parkinson's disease (PD) on patients’ experiences of daily living. There are 13 questions. Part IA is administered by the rater (six questions) and focuses on complex behaviors. Part IB is a component of the self-administered Patient Questionnaire that covers seven questions on non-motor experiences of daily living.

Part IA:

In administering Part IA, the examiner should use the following guidelines:

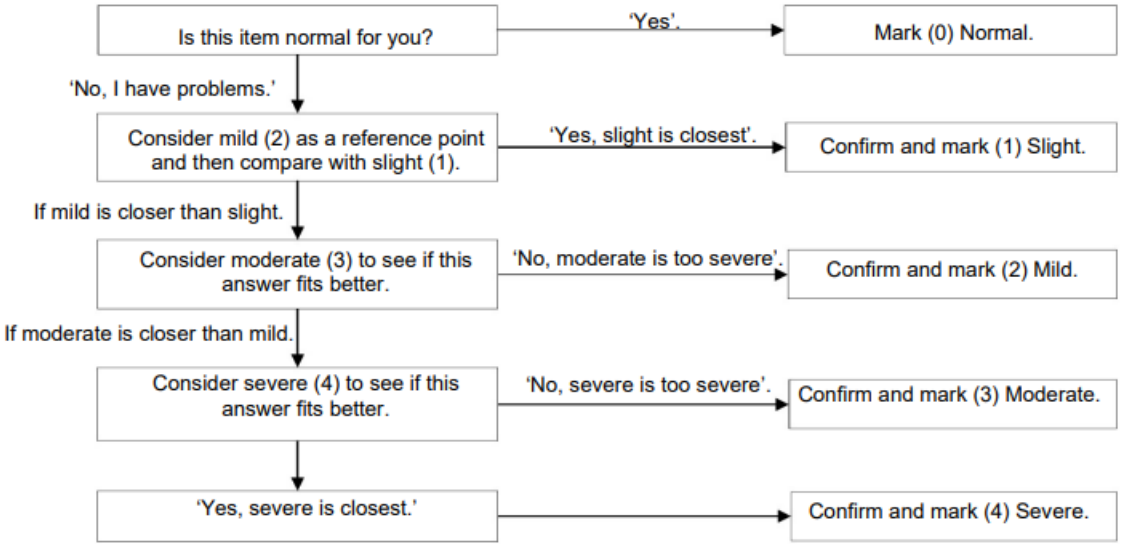
1. Mark at the top of the form the primary data source as patient, caregiver, or patient and caregiver in equal proportion.
2. The response to each item should refer to a period encompassing the prior week including the day on which the information is collected.
3. All items must have an integer rating (no half points, no missing scores). In the event that an item does not apply or cannot be rated (e.g., amputee who cannot walk), the item is marked "**UR**" for Unable to Rate.
4. The answers should reflect the usual level of function and words such as “usually,” “generally,” “most of the time” can be used with patients.
5. Each question has a text for you to read (Instructions to patients/caregiver). After that statement, you can elaborate and probe based on the target symptoms outlined in the Instructions to examiner. You should NOT READ the RATING OPTIONS to the patient/caregiver, because these are written in medical terminology. From the interview and probing, you will use your medical judgment to arrive at the best response.
6. Patients may have co-morbidities and other medical conditions that can affect their function. You and the patient must rate the problem as it exists and do not attempt to separate elements due to Parkinson’s disease from other conditions.

EXAMPLE OF NAVIGATING THROUGH THE RESPONSE OPTIONS FOR PART IA

Suggested strategies for obtaining the most accurate answer: After reading the instructions to the patient, you will need to probe the entire domain under discussion to determine normal vs. problematic: If your questions do not identify any problem in this domain, record 0 and move on to the next question.

If your questions identify a problem in this domain, you should work next with a reference anchor at the mid-range (option 2 or Mild) to find out if the patient functions at this level, better or worse. You will not be reading the choices of responses to the patient as the responses use clinical terminology. You will be asking enough probing questions to determine the response that should be coded.

Work up and down the options with the patient to identify the most accurate response, giving a final check by excluding the options above and below the selected response.



Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Part IA: Complex behaviors: [completed by rater]

To be read to the patient: I am going to ask you six questions about behaviors that you may or may not experience. Some questions concern common problems and some concern uncommon ones. If you have a problem in one of the areas, please choose the best response that describes how you have felt MOST OF THE TIME during the PAST WEEK. If you are not bothered by a problem, you can simply respond NO. I am trying to be thorough, so I may ask questions that have nothing to do with you.

Primary Source of Information:

○ Patient ○ Caregiver ○ Patient and Caregiver in Equal Proportion

1.1 COGNITIVE IMPAIRMENT

Instructions to examiner: Consider all types of altered level of cognitive function including cognitive slowing, impaired reasoning, memory loss, deficits in attention and orientation. Rate their impact on activities of daily living as perceived by the patient and/or caregiver.

Instructions to patient [and caregiver]: Over the past week have you had problems remembering things, following conversations, paying attention, thinking clearly, or finding your way around the house or in town? [If yes, examiner asks patient or caregiver to elaborate and probes for information.]

○ 0: Normal: No cognitive impairment.

○ 1: Slight: Impairment appreciated by patient or caregiver with no concrete interference with the patient's ability to carry out normal activities and social interactions.

○ 2: Mild: Clinically evident cognitive dysfunction, but only minimal interference with the patient's ability to carry out normal activities and social interactions.

○ 3: Moderate: Cognitive deficits interfere with but do not preclude the patient's ability to carry out normal activities and social interactions.

○ 4: Severe: Cognitive dysfunction precludes the patient's ability to carry out normal activities and social interactions.

○ UR: Unable to Rate.

1.2 HALLUCINATIONS AND PSYCHOSIS

Instructions to examiner: Consider both illusions (misinterpretations of real stimuli) and hallucinations (spontaneous false sensations). Consider all major sensory domains (visual, auditory, tactile, olfactory, and gustatory). Determine presence of unformed (for example sense of presence or fleeting false impressions) as well as formed (fully developed and detailed) sensations. Rate the patient's insight into hallucinations and identify delusions and psychotic thinking.

Instructions to patient [and caregiver]: Over the past week have you seen, heard, smelled, or felt things that were not really there? [If yes, examiner asks patient or caregiver to elaborate and probes for information.]

○ 0: Normal: No hallucinations or psychotic behavior.

○ 1: Slight: Illusions or non-formed hallucinations, but patient recognizes them without loss of insight.

○ 2: Mild: Formed hallucinations independent of environmental stimuli. No loss of insight.

○ 3: Moderate: Formed hallucinations with loss of insight.

○ 4: Severe: Patient has delusions or paranoia.

○ UR: Unable to Rate.

1.3 DEPRESSED MOOD

Instructions to examiner: Consider low mood, sadness, hopelessness, feelings of emptiness, or loss of enjoyment. Determine their presence and duration over the past week and rate their interference with the patient's ability to carry out daily routines and engage in social interactions.

Instructions to patient [and caregiver]: Over the past week have you felt low, sad, hopeless, or unable to enjoy things? If yes, was this feeling for longer than one day at a time? Did it make it difficult for you carry out your usual activities or to be with people? [If yes, examiner asks patient or caregiver to elaborate and probes for information.]

○ 0: Normal: No depressed mood.

○ 1: Slight: Episodes of depressed mood that are not sustained for more than one day at a time. No interference with patient's ability to carry out normal activities and social interactions.

○ 2: Mild: Depressed mood that is sustained over days, but without interference with normal activities and social interactions.

○ 3: Moderate: Depressed mood that interferes with, but does not preclude the patient's ability to carry out normal activities and social interactions.

○ 4: Severe: Depressed mood precludes patient's ability to carry out normal activities and social interactions.

○ UR: Unable to Rate.

1.4 ANXIOUS MOOD

Instructions to examiner: Determine nervous, tense, worried, or anxious feelings (including panic attacks) over the past week and rate their duration and interference with the patient's ability to carry out daily routines and engage in social interactions.

Instructions to patient [and caregiver]: Over the past week have you felt nervous, worried, or tense? If yes, was this feeling for longer than one day at a time? Did it make it difficult for you to follow your usual activities or to be with other people? [If yes, examiner asks patient or caregiver to elaborate and probes for information.]

○ 0: Normal: No anxious feelings.

○ 1: Slight: Anxious feelings present but not sustained for more than one day at a time. No interference with patient's ability to carry out normal activities and social interactions.

○ 2: Mild: Anxious feelings are sustained over more than one day at a time, but without interference with patient's ability to carry out normal activities and social interactions.

○ 3: Moderate: Anxious feelings interfere with, but do not preclude, the patient's ability to carry out normal activities and social interactions.

○ 4: Severe: Anxious feelings preclude patient's ability to carry out normal activities and social interactions.

○ UR: Unable to Rate.

1.5 APATHY

Instructions to examiner: Consider level of spontaneous activity, assertiveness, motivation, and initiative and rate the impact of reduced levels on performance of daily routines and social interactions. Here the examiner should attempt to distinguish between apathy and similar symptoms that are best explained by depression.

Instructions to patient [and caregiver]: Over the past week, have you felt indifferent to doing activities or being with people? [If yes, examiner asks patient or caregiver to elaborate and probes for information.]

○ 0: Normal: No apathy.

○ 1: Slight: Apathy appreciated by patient and/or caregiver, but no interference with daily activities and social interactions.

○ 2: Mild: Apathy interferes with isolated activities and social interactions.

○ 3: Moderate: Apathy interferes with most activities and social interactions.

○ 4: Severe: Passive and withdrawn, complete loss of initiative.

○ UR: Unable to Rate.

1.6 FEATURES OF DOPAMINE DYSREGULATION SYNDROME

Instructions to examiner: Consider involvement in a variety of activities including atypical or excessive gambling (e.g. casinos or lottery tickets), atypical or excessive sexual drive or interests (e.g., unusual interest in pornography, masturbation, sexual demands on partner), other repetitive activities (e.g. hobbies, dismantling objects, sorting or organizing), or taking extra non-prescribed medication for non-physical reasons (i.e., addictive behavior). Rate the impact of such abnormal activities/behaviors on the patient's personal life and on his/her family and social relations (including need to borrow money or other financial difficulties like withdrawal of credit cards, major family conflicts, lost time from work, or missed meals or sleep because of the activity).

Instructions to patient [and caregiver]: Over the past week, have you had unusually strong urges that are hard to control? Do you feel driven to do or think about something and find it hard to stop? [Give patient examples such as gambling, cleaning, using the computer, taking extra medicine, obsessing about food or sex, all depending on the patient.]

○ 0: Normal: No problems present.

○ 1: Slight: Problems are present but usually do not cause any difficulties for the patient or family/caregiver.

○ 2: Mild: Problems are present and usually cause a few difficulties in the patient's personal and family life.

○ 3: Moderate: Problems are present and usually cause a lot of difficulties in the patient's personal and family life.

○ 4: Severe: Problems are present and preclude the patient's ability to carry out normal activities or social interactions or to maintain previous standards in personal and family life.

○ UR: Unable to Rate.

The remaining questions in Part I (Non-motor Experiences of Daily Living) [Sleep, Daytime Sleepiness, Pain and Other Sensation, Urinary Problems, Constipation Problems, Lightheadedness on Standing, and Fatigue] are in the **Patient Questionnaire** along with all questions in Part II [Motor Experiences of Daily Living].

PPMI

MDS-UPDRS Part Ib Patient Questionnaire and Part II Patient Questionnaire

Form Instructions:

This questionnaire will ask you about your experiences of daily living.

There are 20 questions. We are trying to be thorough, and some of these questions may therefore not apply to you now or ever. If you do not have the problem, simply mark 0 for NO.

Please read each one carefully and read all answers before selecting the one that best applies to you.

We are interested in your average or usual function over the past week including today. Some patients can do things better at one time of the day than at others. However, only one answer is allowed for each question, so please mark the answer that best describes what you can do most of the time.

You may have other medical conditions besides Parkinson's disease. Do not worry about separating Parkinson's disease from other conditions. Just answer the question with your best response.

Use only 0, 1, 2, 3, 4 for answers, nothing else. Do not leave any blanks.

Your doctor or nurse can review the questions with you, but this questionnaire is for patients to complete, either alone or with their caregivers.

Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Who is filling out this questionnaire? (Choose the best answer):

○ Patient ○ Caregiver ○ Patient and Caregiver in Equal Proportion

Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL)

1.7 SLEEP PROBLEMS

Over the past week, have you had trouble going to sleep at night or staying asleep through the night? Consider how rested you felt after waking up in the morning.

○ 0: Normal: No problems.

○ 1: Slight: Sleep problems are present but usually do not cause trouble getting a full night of sleep.

○ 2: Mild: Sleep problems usually cause some difficulties getting a full night of sleep.

○ 3: Moderate: Sleep problems cause a lot of difficulties getting a full night of sleep, but I still usually sleep for more than half the night.

○ 4: Severe: I usually do not sleep for most of the night.

1.8 DAYTIME SLEEPINESS

Over the past week, have you had trouble staying awake during the daytime?

○ 0: Normal: No daytime sleepiness.

○ 1: Slight: Daytime sleepiness occurs, but I can resist and I stay awake.

○ 2: Mild: Sometimes I fall asleep when alone and relaxing. For example, while reading or watching TV.

○ 3: Moderate: I sometimes fall asleep when I should not. For example, while eating or talking with other people.

○ 4: Severe: I often fall asleep when I should not. For example, while eating or talking with other people.

1.9 PAIN AND OTHER SENSATIONS

Over the past week, have you had uncomfortable feelings in your body like pain, aches, tingling, or cramps?

○ 0: Normal: No uncomfortable feelings.

○ 1: Slight: I have these feelings. However, I can do things and be with other people without difficulty.

○ 2: Mild: These feelings cause some problems when I do things or am with other people.

○ 3: Moderate: These feelings cause a lot of problems, but they do not stop me from doing things or being with other people.

○ 4: Severe: These feelings stop me from doing things or being with other people.

1.10 URINARY PROBLEMS

Over the past week, have you had trouble with urine control? For example, an urgent need to urinate, a need to urinate too often, or urine accidents?

○ 0: Normal: No urine control problems.

○ 1: Slight: I need to urinate often or urgently. However, these problems do not cause difficulties with my daily activities.

○ 2: Mild: Urine problems cause some difficulties with my daily activities. However, I do not have urine accidents.

○ 3: Moderate: Urine problems cause a lot of difficulties with my daily activities, including urine accidents.

○ 4: Severe: I cannot control my urine and use a protective garment or have a bladder tube.

1.11 CONSTIPATION PROBLEMS

Over the past week have you had constipation troubles that cause you difficulty moving your bowels?

○ 0: Normal: No constipation.

○ 1: Slight: I have been constipated. I use extra effort to move my bowels. However, this problem does not disturb my activities or my being comfortable.

○ 2: Mild: Constipation causes me to have some troubles doing things or being comfortable.

○ 3: Moderate: Constipation causes me to have a lot of trouble doing things or being comfortable. However, it does not stop me from doing anything.

○ 4: Severe: I usually need physical help from someone else to empty my bowels.

1.12 LIGHT HEADEDNESS ON STANDING

Over the past week, have you felt faint, dizzy or foggy when you stand up after sitting or lying down?

○ 0: Normal: No dizzy or foggy feelings.

○ 1: Slight: Dizzy or foggy feelings occur. However, they do not cause me troubles doing things.

○ 2: Mild: Dizzy or foggy feelings cause me to hold on to something, but I do not need to sit or lie back down.

○ 3: Moderate: Dizzy or foggy feelings cause me to sit or lie down to avoid fainting or falling.

○ 4: Severe: Dizzy or foggy feelings cause me to fall or faint.

1.13 FATIGUE

Over the past week, have you usually felt fatigued? This feeling is not part of being sleepy or sad.

○ 0: Normal: No fatigue.

○ 1: Slight: Fatigue occurs. However it does not cause me troubles doing things or being with people.

○ 2: Mild: Fatigue causes me some troubles doing things or being with people.

○ 3: Moderate: Fatigue causes me a lot of troubles doing things or being with people. However, it does not stop me from doing anything.

○ 4: Severe: Fatigue stops me from doing things or being with people.

Part II: Motor Aspects of Experiences of Daily Living (M-EDL)

2.1 SPEECH

Over the past week, have you had problems with your speech?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: My speech is soft, slurred or uneven, but it does not cause others to ask me to repeat myself.

○ 2: Mild: My speech causes people to ask me to occasionally repeat myself, but not every day.

○ 3: Moderate: My speech is unclear enough that others ask me to repeat myself every day even though most of my speech is understood.

○ 4: Severe: Most or all of my speech cannot be understood.

2.2 SALIVA AND DROOLING

Over the past week, have you usually had too much saliva during when you are awake or when you sleep?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I have too much saliva, but do not drool.

○ 2: Mild: I have some drooling during sleep, but none when I am awake.

○ 3: Moderate: I have some drooling when I am awake, but I usually do not need tissues or a handkerchief.

○ 4: Severe: I have so much drooling that I regularly need to use tissues or a handkerchief to protect my clothes.

2.3 CHEWING AND SWALLOWING

Over the past week, have you usually had problems swallowing pills or eating meals? Do you need your pills cut or crushed or your meals to be made soft, chopped, or blended to avoid choking?

○ 0: Normal: No problems.

○ 1: Slight: I am aware of slowness in my chewing or increased effort at swallowing, but I do not choke or need to have my food specially prepared.

○ 2: Mild: I need to have my pills cut or my food specially prepared because of chewing or swallowing problems, but I have not choked over the past week.

○ 3: Moderate: I choked at least once in the past week.

○ 4: Severe: Because of chewing and swallowing problems, I need a feeding tube.

2.4 EATING TASKS

Over the past week, have you usually had troubles handling your food and using eating utensils? For example, do you have trouble handling finger foods or using forks, knives, spoons, chopsticks?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am slow, but I do not need any help handling my food and have not had food spills while eating.

○ 2: Mild: I am slow with my eating and have occasional food spills. I may need help with a few tasks such as cutting meat.

○ 3: Moderate: I need help with many eating tasks but can manage some alone.

○ 4: Severe: I need help for most or all eating tasks.

2.5 DRESSING

Over the past week, have you usually had problems dressing? For example, are you slow or do you need help with buttoning, using zippers, putting on or taking off your clothes or jewelry?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am slow, but I do not need help.

○ 2: Mild: I am slow and need help for a few dressing tasks (buttons, bracelets).

○ 3: Moderate: I need help for many dressing tasks.

○ 4: Severe: I need help for most or all dressing tasks.

2.6 HYGIENE

Over the past week, have you usually been slow or do you need help with washing, bathing, shaving, brushing teeth, combing your hair, or with other personal hygiene?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am slow, but I do not need any help.

○ 2: Mild: I need someone else to help me with some hygiene tasks.

○ 3: Moderate: I need help for many hygiene tasks.

○ 4: Severe: I need help for most or all of my hygiene tasks.

2.7 HANDWRITING

Over the past week, have people usually had trouble reading your handwriting?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: My writing is slow, clumsy or uneven, but all words are clear.

○ 2: Mild: Some words are unclear and difficult to read.

○ 3: Moderate: Many words are unclear and difficult to read.

○ 4: Severe: Most or all words cannot be read.

2.8 DOING HOBBIES AND OTHER ACTIVITIES

Over the past week, have you usually had trouble doing your hobbies or other things that you like to do?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am a bit slow but do these activities easily.

○ 2: Mild: I have some difficulty doing these activities.

○ 3: Moderate: I have major problems doing these activities, but still do most.

○ 4: Severe: I am unable to do most or all of these activities.

2.9 TURNING IN BED

Over the past week, do you usually have trouble turning over in bed?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I have a bit of trouble turning, but I do not need any help

○ 2: Mild: I have a lot of trouble turning and need occasional help from someone else.

○ 3: Moderate: To turn over I often need help from someone else.

○ 4: Severe: I am unable to turn over without help from someone else.

2.10 TREMOR

Over the past week, have you usually had shaking or tremor?

○ 0: Normal: Not at all. I have no shaking or tremor.

○ 1: Slight: Shaking or tremor occurs but does not cause problems with any activities.

○ 2: Mild: Shaking or tremor causes problems with only a few activities.

○ 3: Moderate: Shaking or tremor causes problems with many of my daily activities.

○ 4: Severe: Shaking or tremor causes problems with most or all activities.

2.11 GETTING OUT OF BED, A CAR, OR A DEEP CHAIR

Over the past week, have you usually had trouble getting out of bed, a car seat, or a deep chair?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am slow or awkward, but I usually can do it on my first try.

○ 2: Mild: I need more than one try to get up or need occasional help.

○ 3: Moderate: I sometimes need help to get up, but most times I can still do it on my own.

○ 4: Severe: I need help most or all of the time.

2.12 WALKING AND BALANCE

Over the past week, have you usually had problems with balance and walking?

○ 0: Normal: Not at all (no problems).

○ 1: Slight: I am slightly slow or may drag a leg. I never use a walking aid.

○ 2: Mild: I occasionally use a walking aid, but I do not need any help from another person.

○ 3: Moderate: I usually use a walking aid (cane, walker) to walk safely without falling. However, I do not usually need the support of another person.

○ 4: Severe: I usually use the support of another person to walk safely without falling.

2.13 FREEZING

Over the past week, on your usual day when walking, do you suddenly stop or freeze as if your feet are stuck to the floor?

○ 0: Normal: Not at all (no problems)

○ 1: Slight: I briefly freeze, but I can easily start walking again. I do not need help from someone else or a walking aid (cane or walker) because of freezing.

○ 2: Mild: I freeze and have trouble starting to walk again, but I do not need someone's help or a walking aid (cane or walker) because of freezing.

○ 3: Moderate: When I freeze I have a lot of trouble starting to walk again and, because of freezing, I sometimes need to use a walking aid or need someone else's help.

○ 4: Severe: Because of freezing, most or all of the time, I need to use a walking aid or someone's help.

This completes the questionnaire. We may have asked about problems you do not even have, and may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this questionnaire.

PPMI

MDS UPDRS Part IV: Motor Complications

Form Instructions

Overview and Instructions: In this section, the rater uses historical and objective information to assess two motor complications, dyskinesias and motor fluctuations that include OFF-state dystonia. Use all information from patient, caregiver, and the examination to answer the six questions that summarize function over the past week including today. As in the other sections, rate using only integers (no half points allowed) and leave no missing ratings. If the item cannot be rated, place **"UR"** for Unable to Rate. You will need to choose some answers based on percentages, and therefore you will need to establish how many hours the patient is generally awake and use this figure as the denominator for "OFF" time and dyskinesias. For "OFF dystonia", the total "OFF" time will be the denominator. Operational definitions for examiner's use.

Dyskinesias: Involuntary random movements:
Words that patients often recognize for dyskinesias include "irregular jerking", "wiggling", "twitching." It is essential to stress to the patient the difference between dyskinesias and tremor, a common error when patients are assessing dyskinesias.

Dystonia: Contorted posture, often with a twisting component:
Words that patients often recognize for dystonia include "spasms", "cramps", "posture".

Motor fluctuation: Variable response to medication:
Words that patients often recognize for motor fluctuation include "wearing out", "wearing off", "roller-coaster effect", "on-off", "uneven medication effects."

OFF: Typical functional state when patients have a poor response in spite of taking mediation or the typical functional response when patients are on NO treatment for parkinsonism. Words that patients often recognize include "low time", "bad time", "shaking time", "slow time", "time when my medications don't work."

ON: Typical functional state when patients are receiving medication and have a good response:
Words that patients often recognize include "good time", "walking time", "time when my medications work."

Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

A. DYSKINESIAS [exclusive of OFF-state dystonia]

4.1 TIME SPENT WITH DYSKINESIAS

Instructions to examiner: Determine the hours in the usual waking day and then the hours of dyskinesias. Calculate the percentage. If the patient has dyskinesias in the office, you can point them out as a reference to ensure that patients and caregivers understand what they are rating. You may also use your own acting skills to enact the dyskinetic movements you have seen in the patient before or show them dyskinetic movements typical of other patients. Exclude from this question early morning and nighttime painful dystonia.

Instructions to patient [and caregiver]: Over the past week, how many hours do you usually sleep on a daily basis, including nighttime sleep and daytime napping? Alright, if you sleep ___ hrs, you are awake ____ hrs. Out of those awake hours, how many hours in total do you have wiggling, twitching, or jerking movements? Do not count the times when you have tremor, which is a regular back and forth shaking or times when you have painful foot cramps or spasms in the early morning or at nighttime. I will ask about those later. Concentrate only on these types of wiggling, jerking, and irregular movements. Add up all the time during the waking day when these usually occur. How many hours ____ (use this number for your calculations).

1. Total Hours Awake: _____
2. Total Hours with Dyskinesia: _____
3. % Dyskinesia = ((2/1)*100): _____

Score

○ 0: Normal: No dyskinesias.

○ 1: Slight: ≤ 25% of waking day.

○ 2: Mild: 26 - 50% of waking day.

○ 3: Moderate: 51 - 75% of waking day.

○ 4: Severe: > 75% of waking day.

○ UR: Unable to Rate.

4.2 FUNCTIONAL IMPACT OF DYSKINESIAS

Instructions to examiner: Determine the degree to which dyskinesias impact on the patient's daily function in terms of activities and social interactions. Use the patient's and caregiver's response to your question and your own observations during the office visit to arrive at the best answer.

Instructions to patient [and caregiver]: Over the past week, did you usually have trouble doing things or being with people when these jerking movements occurred? Did they stop you from doing things or from being with people?

○ 0: Normal: No dyskinesias or no impact by dyskinesias on activities or social interactions.

○ 1: Slight: Dyskinesias impact on a few activities, but the patient usually performs all activities and participates in all social interactions during dyskinetic periods.

○ 2: Mild: Dyskinesias impact on many activities, but the patient usually performs all activities and participates in all social interactions during dyskinetic periods.

○ 3: Moderate: Dyskinesias impact on activities to the point that the patient usually does not perform some activities or does not usually participate in some social activities during dyskinetic episodes.

○ 4: Severe: Dyskinesias impact on function to the point that the patient usually does not perform most activities or participate in most social interactions during dyskinetic episodes.

○ UR: Unable to Rate.

B. MOTOR FLUCTUATIONS

4.3 TIME SPENT IN THE OFF STATE

Instructions to examiner: Use the number of waking hours derived from 4.1 and determine the hours spent in the "OFF" state. Calculate the percentage. If the patient has an OFF period in the office, you can point to this state as a reference. You may also use your knowledge of the patient to describe a typical OFF period. Additionally you may use your own acting skills to enact an OFF period you have seen in the patient before or show them OFF function typical of other patients. Mark down the typical number of OFF hours, because you will need this number for completing 4.6.

Instructions to patient [and caregiver]: Some patients with Parkinson's disease have a good effect from their medications throughout their awake hours and we call that "ON" time. Other patients take their medications but still have some hours of low time, bad time, slow time, or shaking time. Doctors call these low periods "OFF" time. Over the past week, you told me before that you are generally awake ____ hrs each day. Out of these awake hours, how many hours in total do you usually have this type of low level or OFF function? ____ (use this number for your calculations).

1. Total Hours Awake: _____
2. Total Hours OFF: _____
3. % OFF = ((2/1)*100): _____

Score

○ 0: Normal: No OFF time.

○ 1: Slight: ≤ 25% of waking day.

○ 2: Mild: 26 - 50% of waking day.

○ 3: Moderate: 51 - 75% of waking day.

○ 4: Severe: > 75% of waking day.

○ UR: Unable to Rate.

4.4 FUNCTIONAL IMPACT OF FLUCTUATIONS

Instructions to examiner: Determine the degree to which motor fluctuations impact on the patient's daily function in terms of activities and social interactions. This question concentrates on the difference between the ON state and the OFF state. If the patient has no OFF time, the rating must be 0, but if patients have very mild fluctuations, it is still possible to be rated 0 on this item if no impact on activities occurs. Use the patient's and caregiver's response to your question and your own observations during the office visit to arrive at the best answer.

Instructions to patient [and caregiver]: Think about when those low or "OFF" periods have occurred over the past week. Do you usually have more problems doing things or being with people than compared to the rest of the day when you feel your medications working? Are there some things you usually do during a good period that you have trouble with or stop doing during a low period?

○ 0: Normal: No fluctuations or no impact by fluctuations on performance of activities or social interactions.

○ 1: Slight: Fluctuations impact on a few activities, but during OFF, the patient usually performs all activities and participates in all social interactions that typically occur during the ON state.

○ 2: Mild: Fluctuations impact many activities, but during OFF, the patient still usually performs all activities and participates in all social interactions that typically occur during the ON state.

○ 3: Moderate: Fluctuations impact on the performance of activities during OFF to the point that the patient usually does not perform some activities or participate in some social interactions that are performed during ON periods.

○ 4: Severe: Fluctuations impact on function to the point that, during OFF, the patient usually does not perform most activities or participate in most social interactions that are performed during ON periods.

○ UR: Unable to Rate

4.5 COMPLEXITY OF MOTOR FLUCTUATIONS

Instructions to examiner: Determine the usual predictability of OFF function whether due to dose, time of day, food intake, or other factors. Use the information provided by the patients and caregivers and supplement with your own observations. You will ask if the patient can count on them always coming at a special time, mostly coming at a special time (in which case you will probe further to separate slight from mild), only sometimes coming at a special time, or are they totally unpredictable? Narrowing down the percentage will allow you to find the correct answer.

Instructions to patient [and caregiver]: For some patients, the low or "OFF" periods happen at certain times during day or when they do activities like eating or exercising. Over the past week, do you usually know when your low periods will occur? In other words, do your low periods always come at a certain time? Do they mostly come at a certain time? Do they only sometimes come at a certain time? Are your low periods totally unpredictable?"

○ 0: Normal: No motor fluctuations.

○ 1: Slight: OFF times are predictable all or almost all of the time (> 75%).

○ 2: Mild: OFF times are predictable most of the time (51-75%).

○ 3: Moderate: OFF times are predictable some of the time (26-50%).

○ 4: Severe: OFF episodes are rarely predictable (≤ 25%).

○ UR: Unable to Rate

C. "OFF" DYSTONIA

4.6 PAINFUL OFF-STATE DYSTONIA

Instructions to examiner: For patients who have motor fluctuations, determine what proportion of the OFF episodes usually includes painful dystonia? You have already determined the number of hours of "OFF" time (4.3). Of these hours, determine how many are associated with dystonia and calculate the percentage. If there is no OFF time, mark 0.

Instructions to patient [and caregiver]: In one of the questions I asked earlier, you said you generally have ____ hours of low or "OFF" time when your Parkinson's disease is under poor control. During these low or "OFF" periods, do you usually have painful cramps or spasms? Out of the total ____ hrs of this low time, if you add up all the time in a day when these painful cramps come, how many hours would this make?

1. Total Hours OFF: _____
2. Total OFF Hours with Dystonia: _____
3. % OFF Dystonia = ((2/1)*100): _____

Score

○ 0: No dystonia OR NO OFF TIME.

○ 1: ≤ 25% of time in OFF state.

○ 2: 26-50% of time in OFF state.

○ 3: 51-75% of time in OFF state.

○ 4: > 75% of time in OFF state.

○ UR: Unable to Rate

Summary statement to patient: READ TO PATIENT

This completes my rating of your Parkinson's disease. I know the questions and tasks have taken several minutes, but I wanted to be complete and cover all possibilities. In doing so, I may have asked about problems you do not even have, and I may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this scale with me.

PPMI

MDS-UPDRS Part III Treatment Determination and Part III Motor Examination

Form Instructions:

If the participant is not being treated with either DBS and/or dopaminergic medications (levodopa formulations or dopamine agonists), the MDS-UPDRS part III will be performed once.

If the participant is on levodopa, dopamine agonists, or has had DBS, the MDS-UPDRS should be performed in the OFF and ON state as defined below. It is preferred that the OFF exam be performed first.

OFF: Off is the typical functional state when patients have a poor response in spite of taking medications. OFF testing should occur as at least 6 hours post last dose of PD medication or one hour after DBS has been turned off.

ON: On is the typical functional state when patients are receiving medication and have a good response. ON testing should occur at least 1 hour after PD medication dosing, and/or with DBS turned on.

Assessment Date:_____/_____/_____(mm/dd/yyyy)

Treatment Determination:

1. Is the participant on dopaminergic medication (levodopa formulations or dopamine agonists) for treating the symptoms of Parkinson's disease?

   ○ No

   ○ Yes

2. Has the participant had deep brain stimulation for treating the symptoms of Parkinson's disease?

   ○ No

   ○ Yes

If "No" to question 1 and question 2: Move to the Timing Information section and enter the date and time the No Treatment exam was administered, and then complete the "OFF State / No Treatment" Part III exam section.

If "Yes" to question 1 or question 2: Proceed below.

If the motor exam will only be assessed *once* (i.e., not repeated), then either Question 3 OR Question 4 below must be "Yes" to indicate whether the one motor exam will be completed in the OFF state or the ON state.

If the motor exam will be assessed twice (i.e., repeated), then both Question 3 and Question 4 must be "Yes" and the OFF state and ON state motor exams are expected.

3. For participants receiving treatment for PD (medications, DBS or both), will the "OFF" motor exam be performed?

○ Yes

○ No

i. If no, please select the reason:

○ Disease severity preventing participant from staying off medications/turning off DBS

○ Participant forgot to refrain from taking medications and cannot stay long enough to reverse the order of testing

○ Participant does not feel comfortable turning off DBS

○ Participant/Site forgot to turn off DBS

○ Participant forgot to bring DBS remote to visit

○ Investigator was unable to determine if participant was fully OFF (extended release medication formulations, etc.)

○ Site scheduling issues during completion of visit

○ Other reason, specify:

_____

_____

_____

4. For participants receiving treatment for PD (medications, DBS or both), will the "ON" motor exam be performed?

○ Yes

○ No

i. If no, please select the reason:

○ Typical "ON" state was not reached

○ Scheduling issues

○ Participant did not bring medication to clinic to turn ON

○ Participant forgot to bring DBS remote to visit

○ Other reason, specify:

_____

_____

_____

5. Has the participant undergone high-intensity focused ultrasound (Hi-FU) for treating the symptoms of Parkinson's disease?
   - ○ No
   - ○ Yes
6. Willl the **first** MDS-UPDRS Part III be an "OFF" or "ON" examination??
   - ○ OFF
   - ○ ON

MDS-UPDRS Timing Information:

If question 1 and 2 are "No", enter the information below, and then complete the "OFF State / No Treatment" Part III exam section.

For the No Treatment MDS-UPDRS Part III:

Date that the MDS-UPDRS part III "No Treatment" exam was administered:

____ /____/_____(mm/dd/yyyy)

Time that the MDS-UPDRS part III "No Treatment" exam was administered:

____:____(24-hour clock)

If question 3 is "Yes", enter the information below, and then complete the "OFF State / No Treatment" Part III exam section.

For the OFF MDS-UPDRS Part III:

Date of most recent PD medication dosing:

____ /____/_____(mm/dd/yyyy)

Time of most recent PD medication dosing prior to MDS-UPDRS part III being assessed:

____:____(24-hour clock)

Time that DBS was turned off:

____:____(24-hour clock)

Date that the MDS-UPDRS part III "OFF" exam was administered:

____ /____/_____(mm/dd/yyyy)

Time that the MDS-UPDRS part III "OFF" exam was administered:

____:____(24-hour clock)

MDS-UPDRS Part III Exam – OFF State / No Treatment

Instructions:

This section ("OFF State / No Treatment") should be completed only when A) the participant is not being treated with either DBS or dopaminergic medications or B) the participant is being treated with DBS and/or dopaminergic medications **and** is currently in the OFF state, the typical functional state when patients have a poor response in spite of taking medications.

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

The investigator should "rate what you see." Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), select "Unable to Rate". Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

3.1 SPEECH – OFF

Instructions to examiner: Listen to the patient's free-flowing speech and engage in conversation if necessary. Suggested topics: ask about the patient's work, hobbies, exercise, or how he got to the doctor's office. Evaluate volume, modulation (prosody), and clarity, including slurring, palilalia (repetition of syllables), and tachyphemia (rapid speech, running syllables together).

○ 0: Normal: No speech problems.

○ 1: Slight: Loss of modulation, diction, or volume, but still all words easy to understand.

○ 2: Mild: Loss of modulation, diction, or volume, with a few words unclear, but the overall sentences easy to follow.

○ 3: Moderate: Speech is difficult to understand to the point that some, but not most, sentences are poorly understood.

○ 4: Severe: Most speech is difficult to understand or unintelligible.

○ UR: Unable to Rate.

3.2 FACIAL EXPRESSION – OFF

Instructions to examiner: Observe the patient sitting at rest for 10 seconds, without talking and also while talking. Observe eye-blink frequency, masked facies or loss of facial expression, spontaneous smiling, and parting of lips.

○ 0: Normal: Normal facial expression

○ 1: Slight: Minimal masked facies manifested only by decreased frequency of blinking.

○ 2: Mild: In addition to decreased eye-blink frequency, masked facies present in the lower face as well, namely fewer movements around the mouth, such as less spontaneous smiling, but lips not parted.

○ 3: Moderate: Masked facies with lips parted some of the time when the mouth is at rest.

○ 4: Severe: Masked facies with lips parted most of the time when the mouth is at rest.

○ UR: Unable to Rate.

3.3 RIGIDITY – OFF

Instructions to examiner: Rigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity.

Neck

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

RUE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

LUE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

RLE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

LLE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

3.4 FINGER TAPPING – OFF

Instructions to examiner: Each hand is tested separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to tap the index finger on the thumb 10 times as quickly AND as big as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.5 HAND MOVEMENTS – OFF

Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to make a tight fist with the arm bent at the elbow so that the palm faces the examiner. Have the patient open the hand 10 times as fully AND as quickly as possible. If the patient fails to make a tight fist or to open the hand fully, remind him/ her to do so. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.6 PRONATION-SUPINATION MOVEMENTS OF HANDS – OFF

Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to extend the arm out in front of his/her body with the palms down, and then to turn the palm up and down alternately 10 times as fast and as fully as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st supination-pronation sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st supination-pronation sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.7 TOE TAPPING – OFF

Instructions to examiner: Have the patient sit in a straight-backed chair with arms, both feet on the floor. Test each foot separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the heel on the ground in a comfortable position and then tap the toes 10 times as big and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.

○ UR: Unable to Rate.

3.8 LEG AGILITY – OFF

Instructions to examiner: Have the patient sit in a straight-backed chair with arms. The patient should have both feet comfortably on the floor. Test each leg separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the foot on the ground in a comfortable position and then raise and stomp the foot on the ground 10 times as high and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.9 ARISING FROM CHAIR – OFF

Instructions to examiner: Have the patient sit in a straight-backed chair with arms, with both feet on the floor and sitting back in the chair (if the patient is not too short). Ask the patient to cross his/her arms across the chest and then to stand up. If the patient is not successful, repeat this attempt up to a maximum of two more times. If still unsuccessful, allow the patient to move forward in the chair to arise with arms folded across the chest. Allow only one attempt in this situation. If unsuccessful, allow the patient to push off using his/her hands on the arms of the chair. Allow a maximum of three trials of pushing off. If still not successful, assist the patient to arise. After the patient stands up, observe the posture for item 3.13.

○ 0: Normal: No problems. Able to arise quickly without hesitation

○ 1: Slight: Arising is slower than normal; or may need more than one attempt; or may need to move forward in the chair to arise. No need to use the arms of the chair.

○ 2: Mild: Pushes self up from the arms of the chair without difficulty.

○ 3: Moderate: Needs to push off, but tends to fall back; or may have to try more than one time using the arms of the chair, but can get up without help.

○ 4: Severe: Unable to arise without help.

○ UR: Unable to Rate.

3.10 GAIT – OFF

Instructions to examiner: Testing gait is best performed by having the patient walking away from and towards the examiner so that both right and left sides of the body can be easily observed simultaneously. The patient should walk at least 10 meters (30 feet), then turn around and return to the examiner. This item measures multiple behaviors: stride amplitude, stride speed, height of foot lift, heel strike during walking, turning, and arm swing, but not freezing. Assess also for “freezing of gait” (next item 3.11) while patient is walking. Observe posture for item 3.13.

○ 0: Normal: No problems.

○ 1: Slight: Independent walking with minor gait impairment.

○ 2: Mild: Independent walking but with substantial gait impairment.

○ 3: Moderate: Requires an assistance device for safe walking (walking stick, walker) but not a person.

○ 4: Severe: Cannot walk at all or only with another person’s assistance.

○ UR: Unable to Rate.

3.11 FREEZING OF GAIT – OFF

Instructions to examiner: While assessing gait, also assess for the presence of any gait freezing episodes. Observe for start hesitation and stuttering movements especially when turning and reaching the end of the task. To the extent that safety permits, patients may NOT use sensory tricks during the assessment.

○ 0: Normal: No freezing.

○ 1: Slight: Freezes on starting, turning, or walking through doorway with a single halt during any of these events, but then continues smoothly without freezing during straight walking.

○ 2: Mild: Freezes on starting, turning, or walking through doorway with more than one halt during any of these activities, but continues smoothly without freezing during straight walking.

○ 3: Moderate: Freezes once during straight walking.

○ 4: Severe: Freezes multiple times during straight walking.

○ UR: Unable to Rate.

3.12 POSTURAL STABILITY – OFF

Instructions to examiner: The test examines the response to sudden body displacement produced by a quick, forceful pull on the shoulders while the patient is standing erect with eyes open and feet comfortably apart and parallel to each other. Test retropulsion. Stand behind the patient and instruct the patient on what is about to happen. Explain that s/he is allowed to take a step backwards to avoid falling. There should be a solid wall behind the examiner, at least 1-2 meters away to allow for the observation of the number of retropulsive steps. The first pull is an instructional demonstration and is purposely milder and not rated. The second time the shoulders are pulled briskly and forcefully towards the examiner with enough force to displace the center of gravity so that patient MUST take a step backwards. The examiner needs to be ready to catch the patient, but must stand sufficiently back so as to allow enough room for the patient to take several steps to recover independently. Do not allow the patient to flex the body abnormally forward in anticipation of the pull. Observe for the number of steps backwards or falling. Up to and including two steps for recovery is considered normal, so abnormal ratings begin with three steps. If the patient fails to understand the test, the examiner can repeat the test so that the rating is based on an assessment that the examiner feels reflects the patient's limitations rather than misunderstanding or lack of preparedness. Observe standing posture for item 3.13.

○ 0: Normal: No problems. Recovers with one or two steps.

○ 1: Slight: 3-5 steps, but subject recovers unaided.

○ 2: Mild: More than 5 steps, but subject recovers unaided.

○ 3: Moderate: Stands safely, but with absence of postural response; falls if not caught by examiner.

○ 4: Severe: Very unstable, tends to lose balance spontaneously or with just a gentle pull on the shoulders.

○ UR: Unable to Rate.

3.13 POSTURE – OFF

Instructions to examiner: Posture is assessed with the patient standing erect after arising from a chair, during walking, and while being tested for postural reflexes. If you notice poor posture, tell the patient to stand up straight and see if the posture improves (see option 2 below). Rate the worst posture seen in these three observation points. Observe for flexion and side-to-side leaning.

○ 0: Normal: No problems.

○ 1: Slight: Not quite erect, but posture could be normal for older person.

○ 2: Mild: Definite flexion, scoliosis or leaning to one side, but patient can correct posture to normal posture when asked to do so.

○ 3: Moderate: Stooped posture, scoliosis or leaning to one side that cannot be corrected volitionally to a normal posture by the patient.

○ 4: Severe: Flexion, scoliosis or leaning with extreme abnormality of posture.

○ UR: Unable to Rate.

3.14 GLOBAL SPONTANEITY OF MOVEMENT (BODY BRADYKINESIA) – OFF

Instructions to examiner: This global rating combines all observations on slowness, hesitancy, and small amplitude and poverty of movement in general, including a reduction of gesturing and of crossing the legs. This assessment is based on the examiner's global impression after observing for spontaneous gestures while sitting, and the nature of arising and walking.

○ 0: Normal: No problems.

○ 1: Slight: Slight global slowness and poverty of spontaneous movements.

○ 2: Mild: Mild global slowness and poverty of spontaneous movements.

○ 3: Moderate: Moderate global slowness and poverty of spontaneous movements.

○ 4: Severe: Severe global slowness and poverty of spontaneous movements.

○ UR: Unable to Rate.

3.15 POSTURAL TREMOR OF THE HANDS – OFF

Instructions to examiner: All tremor, including re-emergent rest tremor, that is present in this posture is to be included in this rating. Rate each hand separately. Rate the highest amplitude seen. Instruct the patient to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other. Observe this posture for 10 seconds.

Right

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

Left

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

3.16 KINETIC TREMOR OF THE HANDS – OFF

Instructions to examiner: This is tested by the finger-to-nose maneuver. With the arm starting from the outstretched position, have the patient perform at least three finger-to-nose maneuvers with each hand reaching as far as possible to touch the examiner's finger. The finger-to-nose maneuver should be performed slowly enough not to hide any tremor that could occur with very fast arm movements. Repeat with the other hand, rating each hand separately. The tremor can be present throughout the movement or as the tremor reaches either target (nose or finger). Rate the highest amplitude seen.

Right

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

Left

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

3.17 REST TREMOR AMPLITUDE – OFF

Instructions to examiner: This and the next item have been placed purposefully at the end of the examination to allow the rater to gather observations on rest tremor that may appear at any time during the exam, including when quietly sitting, during walking, and during activities when some body parts are moving but others are at rest. Score the maximum amplitude that is seen at any time as the final score. Rate only the amplitude and not the persistence or the intermittency of the tremor.
As part of this rating, the patient should sit quietly in a chair with the hands placed on the arms of the chair (not in the lap) and the feet comfortably supported on the floor for 10 seconds with no other directives. Rest tremor is assessed separately for all four limbs and also for the lip/jaw. Rate only the maximum amplitude that is seen at any time as the final rating.

Extremity ratings

RUE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

LUE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

RLE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

LLE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

Lip/Jaw Ratings

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 2 cm in maximal amplitude.

○ 3: Moderate: ≥ 2 cm but < 3 cm in maximal amplitude.

○ 4: Severe: ≥ 3 cm in maximal amplitude.

○ UR: Unable to Rate.

3.18 CONSTANCY OF REST TREMOR – OFF

Instructions to examiner: This item receives one rating for all rest tremor and focuses on the constancy of rest tremor during the examination period when different body parts are variously at rest. It is rated purposefully at the end of the examination so that several minutes of information can be coalesced into the rating.

○ 0: Normal: No tremor.

○ 1: Slight: Tremor at rest is present ≤ 25% of the entire examination period.

○ 2: Mild: Tremor at rest is present 26-50% of the entire examination period.

○ 3: Moderate: Tremor at rest is present 51-75% of the entire examination period.

○ 4: Severe: Tremor at rest is present > 75% of the entire examination period.

○ UR: Unable to Rate.

DYSKINESIA IMPACT ON PART III RATINGS – OFF

A. Were dyskinesias (chorea or dystonia) present during examination?

○ No ○ Yes

B. If yes, did these movements interfere with your ratings?

○ No ○ Yes

HOEHN AND YAHR STAGE – OFF

○ 0: Asymptomatic.

○ 1: Unilateral involvement only.

○ 2: Bilateral involvement without impairment of balance.

○ 3: Mild to moderate involvement; some postural instability but physically independent; needs assistance to recover from pull test.

○ 4: Severe disability; still able to walk or stand unassisted.

○ 5: Wheelchair bound or bedridden unless aided.

○ UR: Unable to Rate.

If question 4 is “Yes”, enter the information below, and then complete the “ON State” Part III exam section.

For the ON MDS-UPDRS Part III:

Date of most recent PD medication dosing:

_____ /____/_____(mm/dd/yyyy)

Time of most recent/in clinic PD medication dosing:

_____:_____(24-hour clock)

Time that DBS was turned on:

_____:_____(24-hour clock)

Date that the MDS-UPDRS part III “ON” exam was administered:

_____ /____/_____(mm/dd/yyyy)

Time that the MDS-UPDRS part III “ON” exam was administered:

_____:_____(24-hour clock)

MDS-UPDRS Part III Exam – ON State

Instructions:

This section ("ON State") should be completed only when the participant is being treated with either DBS and/or dopaminergic medications and is currently in the ON state, the typical functional state when patients are receiving medication and have a good response.

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

The investigator should "rate what you see." Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), select "Unable to Rate". Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

3.1 SPEECH – ON

Instructions to examiner: Listen to the patient's free-flowing speech and engage in conversation if necessary. Suggested topics: ask about the patient's work, hobbies, exercise, or how he got to the doctor's office. Evaluate volume, modulation (prosody), and clarity, including slurring, palilalia (repetition of syllables), and tachyphemia (rapid speech, running syllables together).

○ 0: Normal: No speech problems.

○ 1: Slight: Loss of modulation, diction, or volume, but still all words easy to understand.

○ 2: Mild: Loss of modulation, diction, or volume, with a few words unclear, but the overall sentences easy to follow.

○ 3: Moderate: Speech is difficult to understand to the point that some, but not most, sentences are poorly understood.

○ 4: Severe: Most speech is difficult to understand or unintelligible.

○ UR: Unable to Rate.

3.2 FACIAL EXPRESSION – ON

Instructions to examiner: Observe the patient sitting at rest for 10 seconds, without talking and also while talking. Observe eye-blink frequency, masked facies or loss of facial expression, spontaneous smiling, and parting of lips.

○ 0: Normal: Normal facial expression

○ 1: Slight: Minimal masked facies manifested only by decreased frequency of blinking.

○ 2: Mild: In addition to decreased eye-blink frequency, masked facies present in the lower face as well, namely fewer movements around the mouth, such as less spontaneous smiling, but lips not parted.

○ 3: Moderate: Masked facies with lips parted some of the time when the mouth is at rest.

○ 4: Severe: Masked facies with lips parted most of the time when the mouth is at rest.

○ UR: Unable to Rate.

3.3 RIGIDITY – ON

Instructions to examiner: Rigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity.

Neck

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

RUE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

LUE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

RLE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

LLE

○ 0: Normal: No rigidity.

○ 1: Slight: Rigidity only detected with activation maneuver.

○ 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved.

○ 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort.

○ 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.

○ UR: Unable to Rate.

3.4 FINGER TAPPING – ON

Instructions to examiner: Each hand is tested separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to tap the index finger on the thumb 10 times as quickly AND as big as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.5 HAND MOVEMENTS – ON

Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to make a tight fist with the arm bent at the elbow so that the palm faces the examiner. Have the patient open the hand 10 times as fully AND as quickly as possible. If the patient fails to make a tight fist or to open the hand fully, remind him/ her to do so. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.6 PRONATION-SUPINATION MOVEMENTS OF HANDS – ON

Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to extend the arm out in front of his/her body with the palms down, and then to turn the palm up and down alternately 10 times as fast and as fully as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st supination-pronation sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st supination-pronation sequence.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.7 TOE TAPPING – ON

Instructions to examiner: Have the patient sit in a straight-backed chair with arms, both feet on the floor. Test each foot separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the heel on the ground in a comfortable position and then tap the toes 10 times as big and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts, and decrementing amplitude.

Right

○ 0: Normal: No problems

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.

○ UR: Unable to Rate.

3.8 LEG AGILITY – ON

Instructions to examiner: Have the patient sit in a straight-backed chair with arms. The patient should have both feet comfortably on the floor. Test each leg separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the foot on the ground in a comfortable position and then raise and stomp the foot on the ground 10 times as high and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

Right

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

Left

○ 0: Normal: No problems.

○ 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task.

○ 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task.

○ 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the 1st tap.

○ 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions, or decrements.

○ UR: Unable to Rate.

3.9 ARISING FROM CHAIR – ON

Instructions to examiner: Have the patient sit in a straight-backed chair with arms, with both feet on the floor and sitting back in the chair (if the patient is not too short). Ask the patient to cross his/her arms across the chest and then to stand up. If the patient is not successful, repeat this attempt up to a maximum of two more times. If still unsuccessful, allow the patient to move forward in the chair to arise with arms folded across the chest. Allow only one attempt in this situation. If unsuccessful, allow the patient to push off using his/her hands on the arms of the chair. Allow a maximum of three trials of pushing off. If still not successful, assist the patient to arise. After the patient stands up, observe the posture for item 3.13.

○ 0: Normal: No problems. Able to arise quickly without hesitation

○ 1: Slight: Arising is slower than normal; or may need more than one attempt; or may need to move forward in the chair to arise. No need to use the arms of the chair.

○ 2: Mild: Pushes self up from the arms of the chair without difficulty.

○ 3: Moderate: Needs to push off, but tends to fall back; or may have to try more than one time using the arms of the chair, but can get up without help.

○ 4: Severe: Unable to arise without help.

○ UR: Unable to Rate.

3.10 GAIT – ON

Instructions to examiner: Testing gait is best performed by having the patient walking away from and towards the examiner so that both right and left sides of the body can be easily observed simultaneously. The patient should walk at least 10 meters (30 feet), then turn around and return to the examiner. This item measures multiple behaviors: stride amplitude, stride speed, height of foot lift, heel strike during walking, turning, and arm swing, but not freezing. Assess also for "freezing of gait" (next item 3.11) while patient is walking. Observe posture for item 3.13.

○ 0: Normal: No problems.

○ 1: Slight: Independent walking with minor gait impairment.

○ 2: Mild: Independent walking but with substantial gait impairment.

○ 3: Moderate: Requires an assistance device for safe walking (walking stick, walker) but not a person.

○ 4: Severe: Cannot walk at all or only with another person's assistance.

○ UR: Unable to Rate.

3.11 FREEZING OF GAIT – ON

Instructions to examiner: While assessing gait, also assess for the presence of any gait freezing episodes. Observe for start hesitation and stuttering movements especially when turning and reaching the end of the task. To the extent that safety permits, patients may NOT use sensory tricks during the assessment.

○ 0: Normal: No freezing.

○ 1: Slight: Freezes on starting, turning, or walking through doorway with a single halt during any of these events, but then continues smoothly without freezing during straight walking.

○ 2: Mild: Freezes on starting, turning, or walking through doorway with more than one halt during any of these activities, but continues smoothly without freezing during straight walking.

○ 3: Moderate: Freezes once during straight walking.

○ 4: Severe: Freezes multiple times during straight walking.

○ UR: Unable to Rate.

3.12 POSTURAL STABILITY – ON

Instructions to examiner: The test examines the response to sudden body displacement produced by a quick, forceful pull on the shoulders while the patient is standing erect with eyes open and feet comfortably apart and parallel to each other. Test retropulsion. Stand behind the patient and instruct the patient on what is about to happen. Explain that s/he is allowed to take a step backwards to avoid falling. There should be a solid wall behind the examiner, at least 1-2 meters away to allow for the observation of the number of retropulsive steps. The first pull is an instructional demonstration and is purposely milder and not rated. The second time the shoulders are pulled briskly and forcefully towards the examiner with enough force to displace the center of gravity so that patient MUST take a step backwards. The examiner needs to be ready to catch the patient, but must stand sufficiently back so as to allow enough room for the patient to take several steps to recover independently. Do not allow the patient to flex the body abnormally forward in anticipation of the pull. Observe for the number of steps backwards or falling. Up to and including two steps for recovery is considered normal, so abnormal ratings begin with three steps. If the patient fails to understand the test, the examiner can repeat the test so that the rating is based on an assessment that the examiner feels reflects the patient's limitations rather than misunderstanding or lack of preparedness. Observe standing posture for item 3.13.

○ 0: Normal: No problems. Recovers with one or two steps.

○ 1: Slight: 3-5 steps, but subject recovers unaided.

○ 2: Mild: More than 5 steps, but subject recovers unaided.

○ 3: Moderate: Stands safely, but with absence of postural response; falls if not caught by examiner.

○ 4: Severe: Very unstable, tends to lose balance spontaneously or with just a gentle pull on the shoulders.

○ UR: Unable to Rate.

3.13 POSTURE – ON

Instructions to examiner: Posture is assessed with the patient standing erect after arising from a chair, during walking, and while being tested for postural reflexes. If you notice poor posture, tell the patient to stand up straight and see if the posture improves (see option 2 below). Rate the worst posture seen in these three observation points. Observe for flexion and side-to-side leaning.

○ 0: Normal: No problems.

○ 1: Slight: Not quite erect, but posture could be normal for older person.

○ 2: Mild: Definite flexion, scoliosis or leaning to one side, but patient can correct posture to normal posture when asked to do so.

○ 3: Moderate: Stooped posture, scoliosis or leaning to one side that cannot be corrected volitionally to a normal posture by the patient.

○ 4: Severe: Flexion, scoliosis or leaning with extreme abnormality of posture.

○ UR: Unable to Rate.

3.14 GLOBAL SPONTANEITY OF MOVEMENT (BODY BRADYKINESIA) – ON

Instructions to examiner: This global rating combines all observations on slowness, hesitancy, and small amplitude and poverty of movement in general, including a reduction of gesturing and of crossing the legs. This assessment is based on the examiner's global impression after observing for spontaneous gestures while sitting, and the nature of arising and walking.

○ 0: Normal: No problems.

○ 1: Slight: Slight global slowness and poverty of spontaneous movements.

○ 2: Mild: Mild global slowness and poverty of spontaneous movements.

○ 3: Moderate: Moderate global slowness and poverty of spontaneous movements.

○ 4: Severe: Severe global slowness and poverty of spontaneous movements.

○ UR: Unable to Rate.

3.15 POSTURAL TREMOR OF THE HANDS – ON

Instructions to examiner: All tremor, including re-emergent rest tremor, that is present in this posture is to be included in this rating. Rate each hand separately. Rate the highest amplitude seen. Instruct the patient to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other. Observe this posture for 10 seconds.

Right

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

Left

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

3.16 KINETIC TREMOR OF THE HANDS – ON

Instructions to examiner: This is tested by the finger-to-nose maneuver. With the arm starting from the outstretched position, have the patient perform at least three finger-to-nose maneuvers with each hand reaching as far as possible to touch the examiner's finger. The finger-to-nose maneuver should be performed slowly enough not to hide any tremor that could occur with very fast arm movements. Repeat with the other hand, rating each hand separately. The tremor can be present throughout the movement or as the tremor reaches either target (nose or finger). Rate the highest amplitude seen.

Right

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

Left

○ 0: Normal: No tremor.

○ 1: Slight: Tremor is present but less than 1 cm in amplitude.

○ 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude.

○ 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude.

○ 4: Severe: Tremor is at least 10 cm in amplitude.

○ UR: Unable to Rate.

3.17 REST TREMOR AMPLITUDE – ON

Instructions to examiner: This and the next item have been placed purposefully at the end of the examination to allow the rater to gather observations on rest tremor that may appear at any time during the exam, including when quietly sitting, during walking, and during activities when some body parts are moving but others are at rest. Score the maximum amplitude that is seen at any time as the final score. Rate only the amplitude and not the persistence or the intermittency of the tremor.
As part of this rating, the patient should sit quietly in a chair with the hands placed on the arms of the chair (not in the lap) and the feet comfortably supported on the floor for 10 seconds with no other directives. Rest tremor is assessed separately for all four limbs and also for the lip/jaw. Rate only the maximum amplitude that is seen at any time as the final rating.

Extremity ratings

RUE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

LUE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

RLE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

LLE

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 3 cm in maximal amplitude.

○ 3: Moderate: ≥ 3 cm but < 10 cm in maximal amplitude.

○ 4: Severe: ≥ 10 cm in maximal amplitude.

○ UR: Unable to Rate.

Lip/Jaw Ratings

○ 0: Normal: No tremor.

○ 1: Slight: < 1 cm in maximal amplitude.

○ 2: Mild: ≥ 1 cm but < 2 cm in maximal amplitude.

○ 3: Moderate: ≥ 2 cm but < 3 cm in maximal amplitude.

○ 4: Severe: ≥ 3 cm in maximal amplitude.

○ UR: Unable to Rate.

3.18 CONSTANCY OF REST TREMOR – ON

Instructions to examiner: This item receives one rating for all rest tremor and focuses on the constancy of rest tremor during the examination period when different body parts are variously at rest. It is rated purposefully at the end of the examination so that several minutes of information can be coalesced into the rating.

○ 0: Normal: No tremor.

○ 1: Slight: Tremor at rest is present ≤ 25% of the entire examination period.

○ 2: Mild: Tremor at rest is present 26-50% of the entire examination period.

○ 3: Moderate: Tremor at rest is present 51-75% of the entire examination period.

○ 4: Severe: Tremor at rest is present > 75% of the entire examination period.

○ UR: Unable to Rate.

DYSKINESIA IMPACT ON PART III RATINGS – ON

A. Were dyskinesias (chorea or dystonia) present during examination?

○ No ○ Yes

B. If yes, did these movements interfere with your ratings?

○ No ○ Yes

HOEHN AND YAHR STAGE – ON

○ 0: Asymptomatic.

○ 1: Unilateral involvement only.

○ 2: Bilateral involvement without impairment of balance.

○ 3: Mild to moderate involvement; some postural instability but physically independent; needs assistance to recover from pull test.

○ 4: Severe disability; still able to walk or stand unassisted.

○ 5: Wheelchair bound or bedridden unless aided.

○ UR: Unable to Rate.

PPMI

Medical Conditions Log

If the exact date of diagnosis or resolution is unknown, please select the first of the month in the appropriate month and year.

A. Collection Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Category: ☑ ☐
2. Date of Diagnosis: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
3. Diagnosis and Description (Do not abbreviate): _____
4. Resolved: ○ No ○ Yes
5. Date of Resolution: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Modified Boston Naming Test

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Number of spontaneously given correct responses (0-60): _____
2. Number of correct responses following a stimulus cue: _____

PPMI

Modified Schwab & England Activities of Daily Living

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Provide a consensus rating (Investigator, Participant, Caregiver/Informant) using 5-point increments between 0 and 100%.

○ 100%	Completely independent. Able to do all chores without slowness, difficulty or impairment. Essentially normal. Unaware of any difficulty.
○ 95%	
○ 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.
○ 85%	
○ 80%	Completely independent in most chores. Takes twice as long. Conscious of difficulty and slowness.
○ 75%	
○ 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.
○ 65%	
○ 60%	Some dependency. Can do most chores, but exceedingly slowly and with much effort. Errors; some impossible.
○ 55%	
○ 50%	More dependent. Help with half, slower, etc. Difficulty with everything.
○ 45%	
○ 40%	Very dependent. Can assist with all chores but few alone.
○ 35%	
○ 30%	With effort, now and then does a few chores alone or begins alone. Much help needed.
○ 25%	
○ 20%	Nothing alone. Can be a slight help with some chores. Severe invalid.
○ 15%	
○ 10%	Totally dependent, helpless. Complete invalid.
○ 5%	
○ 0%	Vegetative functions such as swallowing, bladder, and bowel functions are not functioning. Bedridden.

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

PPMI

Modified Semantic Fluency

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Total Number of Animals named in one minute (60 seconds): _____

PPMI

Montreal Cognitive Assessment (MoCA)

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

	Section	Score	
	Executive		
1.	Alternating Trail Making:	○ 0	○ 1
	Visuoconstructional Skills		
2.	Cube:	○ 0	○ 1
3.	Clock - Contour:	○ 0	○ 1
4.	Clock - Numbers:	○ 0	○ 1
5.	Clock - Hands:	○ 0	○ 1
	Naming		
6.	Lion:	○ 0	○ 1
7.	Rhinoceros or Rhino:	○ 0	○ 1
8.	Camel or Dromedary:	○ 0	○ 1
	Attention		
9.	Forward Digit Span:	○ 0	○ 1
10.	Backward Digit Span:	○ 0	○ 1

11. Vigilance:

    ○ 0 = 2 or more errors ○ 1 = 0 or 1 errors

12. Serial 7s:

    ○ 0 = 0 correct ○ 1 = 1 correct ○ 2 = 2 or 3 correct ○ 3 = 4 or 5 correct

Language

13. Sentence Repetition: ○ 0 ○ 1 ○ 2
14. Verbal Fluency - Number of words: _____
15. Verbal Fluency - Score: ○ 0 ○ 1 = 11 or more words

Abstraction

16. Abstraction: ○ 0 ○ 1 ○ 2

Delayed recall

17. Face: ○ 0 ○ 1
18. Velvet: ○ 0 ○ 1
19. Church: ○ 0 ○ 1
20. Daisy: ○ 0 ○ 1
21. Red: ○ 0 ○ 1

Orientation

22. Date: ○ 0 ○ 1
23. Month: ○ 0 ○ 1
24. Year: ○ 0 ○ 1
25. Day: ○ 0 ○ 1
26. Place: ○ 0 ○ 1
27. City: ○ 0 ○ 1

PPMI

MRI Waiver

Complete this form to document approval of an MRI waiver by the PPMI medical monitor.

1. Date site requested waiver: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
2. Date site notified of approval: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
3. Description of waiver:

_____

_____

_____

PPMI

Neuro QoL Cognition Function - Short Form

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Form instructions: Please respond to each question or statement by marking one box per row.

How much DIFFICULTY do you currently have…

1. reading and following complex instructions (e.g., directions for a new medication)?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

2. planning for and keeping appointments that are not part of your weekly routine, (e.g., a therapy or doctor appointment, or a social gathering with friends and family)?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

3. managing your time to do most of your daily activities?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

4. learning new tasks or instructions?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

English
March 6, 2014

PPMI

Neuro QoL Communication - Short Form

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Form instructions: Please respond to each question or statement by marking one box per row.

How much DIFFICULTY do you currently have…

1. writing notes to yourself, such as appointments or 'to do' lists?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

2. understanding family and friends on the phone?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

3. carrying on a conversation with a small group of familiar people (e.g., family or a few friends)?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

4. organizing what you want to say?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

5. speaking clearly enough to use the telephone?

   ○ None ○ A little ○ Somewhat ○ A lot ○ Cannot do

English
March 6, 2014

PPMI

Neuro QoL Lower Extremity Function (Mobility) - Short Form

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Form instructions: Please respond to each question or statement by marking one box per row.

1. Are you able to get on and off the toilet?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

2. Are you able to step up and down curbs?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

3. Are you able to get in and out of a car?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

4. Are you able to get out of bed into a chair?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

5. Are you able to push open a heavy door?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

6. Are you able to run errands and shop?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

7. Are you able to get up off the floor from lying on your back without help?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

8. Are you able to go for a walk of at least 15 minutes?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

English
March 6, 2014

PPMI

Neuro QoL Upper Extremity Function (Fine Motor, ADL) - Short Form

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Form Instructions: Please respond to each question or statement by marking one box per row.

1. Are you able to turn a key in a lock?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

2. Are you able to brush your teeth?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

3. Are you able to make a phone call using a touch tone key-pad?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

4. Are you able to pick up coins from a table top?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

5. Are you able to write with a pen or pencil?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

6. Are you able to open and close a zipper?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

7. Are you able to wash and dry your body?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

8. Are you able to shampoo your hair?

   ○ Without any difficulty ○ With a little difficulty ○ With some difficulty ○ With much difficulty ○ Unable to do

English
March 6, 2014

PPMI

Neurological Exam

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Mental Status:
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

2. Cranial Nerves (II –XII):
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

3. Motor Exam (other than PD):
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

4. Sensory Exam:
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

5. Coordination (other than PD):
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

6. Reflexes:
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

7. Gait (other than PD):
   - ○ Normal
   - ○ Abnormal, specify: _____
   - ○ Not tested
   - ○ Unable to test

PPMI

Other Clinical Features

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

I. Other features supportive of Parkinson's disease

1. Stooped posture	○ No	○ Yes	○ Uncertain
2. Decreased arm swing	○ No	○ Yes	○ Uncertain
3. Shuffling gait	○ No	○ Yes	○ Uncertain
4. Micrographia	○ No	○ Yes	○ Uncertain
5. Diminished olfaction	○ No	○ Yes	○ Uncertain
6. Seborrheic dermatitis	○ No	○ Yes	○ Uncertain
7. Dream enactment suggestive of REM sleep behavior disorder	○ No	○ Yes	○ Uncertain

II. Atypical motor features

1. Postural instability or gait freezing in the first 3 years	○ No	○ Yes	○ Uncertain
2. Supranuclear gaze palsy	○ No	○ Yes	○ Uncertain
3. Dysphagia	○ No	○ Yes	○ Uncertain
4. Dysarthria	○ No	○ Yes	○ Uncertain
5. Inspiratory stridor	○ No	○ Yes	○ Uncertain
6. Disproportionate anterocollis	○ No	○ Yes	○ Uncertain
7. Wide based gait / cerebellar features	○ No	○ Yes	○ Uncertain
8. Myoclonous	○ No	○ Yes	○ Uncertain
9. Dystonia	○ No	○ Yes	○ Uncertain
10. Prominent action tremor	○ No	○ Yes	○ Uncertain

III. Neurobehavioral features

1. Cognitive fluctuations	○ No	○ Yes	○ Uncertain
2. Systematized delusions or visual hallucinations unrelated to medications	○ No	○ Yes	○ Uncertain
3. Depression	○ No	○ Yes	○ Uncertain
4. Anxiety	○ No	○ Yes	○ Uncertain
5. Apathy	○ No	○ Yes	○ Uncertain

IV. Other non-motor features associated with atypical parkinsonism

1. Symptomatic dysautonomia unrelated to medications, including:			
1a. postural hypotension	○ No	○ Yes	○ Uncertain
1b. sexual dysfunction	○ No	○ Yes	○ Uncertain
1c. urinary dysfunction	○ No	○ Yes	○ Uncertain
1d. bowel dysfunction	○ No	○ Yes	○ Uncertain
2. Unequivocal cortical sensory loss (i.e., graphesthesia, stereognosis with intact primary sensory modalities)	○ No	○ Yes	○ Uncertain
3. Limb ideomotor apraxia	○ No	○ Yes	○ Uncertain
4. Otherwise unexplained pyramidal tract signs	○ No	○ Yes	○ Uncertain
5. Alien limb phenomenon	○ No	○ Yes	○ Uncertain
6. Definite response to alcohol	○ No	○ Yes	○ Uncertain

V. Response to therapy

1. Clear and dramatic response to levodopa	○ No	○ Yes	○ Not Applicable
2. Little or no response to levodopa	○ No	○ Yes	○ Not Applicable
3. Neuroleptic super-sensitivity	○ No	○ Yes	○ Not Applicable
4. Motor fluctuations	○ No	○ Yes	○ Not Applicable
5. Dyskinesia	○ No	○ Yes	○ Not Applicable

PPMI

Parkinson's Disease Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" for the applicable sections before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria – ALL PD Participants:

1. Male or female age 30 years or older at Screening Visit.

   ○ Yes ○ No

2. Has a clinical diagnosis of Parkinson's disease at Screening Visit.

   ○ Yes ○ No

3. Patients 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.

   ○ Yes ○ No

4. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

6. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

7. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

Additional Inclusion Criteria for Sporadic PD:

8. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

   ○ Yes ○ No

9. Hoehn and Yahr stage I or II at Baseline.

   ○ Yes ○ No

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

    ○ Yes ○ No

11. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD LRRK2 or GBA Variant:

12. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

    ○ Yes ○ No

13. Hoehn and Yahr stage I or II at Baseline.

    ○ Yes ○ No

14. Confirmation of causative LRRK2 or GBA from the PPMI Screening Core.

    ○ Yes ○ No

15. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD SNCA or rare genetic variant such as Parkin or Pink1:

16. Confirmation of causative SNCA or rare genetic variant (such as Parkin or Pink1) from the PPMI Screening Core.

    ○ Yes ○ No

17. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

18. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic:

19. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

20. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic LRRK2:

21. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

22. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

23. Confirmation of causative LRRK2 from the PPMI Screening Core.

    ○ Yes ○ No

Exclusion Criteria – ALL PD Participants:

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).

   ○ No ○ Yes

2. A clinical diagnosis of dementia as determined by the investigator.

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

Additional Exclusion Criteria for Sporadic PD:

9. Receiving treatment for PD, including levodopa, dopamine agonists, MAO-B inhibitors, amantadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor), or Deep Brain Stimulation (DBS).

   ○ No ○ Yes

10. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

    ○ No ○ Yes

11. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

    ○ No ○ Yes

PPMI

Parkinson's Disease Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" for the applicable sections before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria – ALL PD Participants:

1. Male or female age 30 years or older at Screening Visit.

   ○ Yes ○ No

2. Has a clinical diagnosis of Parkinson's disease at Screening Visit.

   ○ Yes ○ No

3. Patients 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.

   ○ Yes ○ No

4. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

6. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

7. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

Additional Inclusion Criteria for Sporadic PD:

8. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

   ○ Yes ○ No

9. Hoehn and Yahr stage I or II at Baseline.

   ○ Yes ○ No

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

    ○ Yes ○ No

11. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD LRRK2 or GBA Variant:

12. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

    ○ Yes ○ No

13. Hoehn and Yahr stage I or II at Baseline.

    ○ Yes ○ No

14. Confirmation of causative LRRK2 or GBA from the PPMI Screening Core.

    ○ Yes ○ No

15. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD SNCA or rare genetic variant such as Parkin or Pink1:

16. Confirmation of causative SNCA or rare genetic variant (such as Parkin or Pink1) from the PPMI Screening Core.

    ○ Yes ○ No

17. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

18. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic:

19. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

20. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic LRRK2:

21. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

22. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

23. Confirmation of causative LRRK2 from the PPMI Screening Core.

    ○ Yes ○ No

Exclusion Criteria – ALL PD Participants:

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).

   ○ No ○ Yes

2. A clinical diagnosis of dementia as determined by the investigator.

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

Additional Exclusion Criteria for Sporadic PD:

9. Receiving treatment for PD, including levodopa, dopamine agonists, MAO-B inhibitors, amantadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor), or Deep Brain Stimulation (DBS).

   ○ No ○ Yes

10. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

    ○ No ○ Yes

11. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

    ○ No ○ Yes

PPMI

Parkinson's Disease Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" for the applicable sections before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria – ALL PD Participants:

1. Male or female age 30 years or older at Screening Visit.

   ○ Yes ○ No

2. Has a clinical diagnosis of Parkinson's disease at Screening Visit.

   ○ Yes ○ No

3. Patients 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.

   ○ Yes ○ No

4. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

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   ○ Yes ○ No

Additional Inclusion Criteria for Sporadic PD:

8. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

   ○ Yes ○ No

9. Hoehn and Yahr stage I or II at Baseline.

   ○ Yes ○ No

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

    ○ Yes ○ No

11. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD LRRK2 or GBA Variant:

12. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

    ○ Yes ○ No

13. Hoehn and Yahr stage I or II at Baseline.

    ○ Yes ○ No

14. Confirmation of causative LRRK2 or GBA from the PPMI Screening Core.

    ○ Yes ○ No

15. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

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Additional Inclusion Criteria for PD SNCA or rare genetic variant such as Parkin or Pink1:

16. Confirmation of causative SNCA or rare genetic variant (such as Parkin or Pink1) from the PPMI Screening Core.

    ○ Yes ○ No

17. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

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    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic:

19. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

20. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic LRRK2:

21. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

22. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

23. Confirmation of causative LRRK2 from the PPMI Screening Core.

    ○ Yes ○ No

Exclusion Criteria – ALL PD Participants:

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).

   ○ No ○ Yes

2. A clinical diagnosis of dementia as determined by the investigator.

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

Additional Exclusion Criteria for Sporadic PD:

9. Receiving treatment for PD, including levodopa, dopamine agonists, MAO-B inhibitors, amantadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor), or Deep Brain Stimulation (DBS).

   ○ No ○ Yes

10. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

    ○ No ○ Yes

11. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

    ○ No ○ Yes

PPMI

Parkinson's Disease Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" for the applicable sections before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria – ALL PD Participants:

1. Male or female age 30 years or older at Screening Visit.

   ○ Yes ○ No

2. Has a clinical diagnosis of Parkinson's disease at Screening Visit.

   ○ Yes ○ No

3. Patients 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.

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4. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

6. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

7. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

Additional Inclusion Criteria for Sporadic PD:

8. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

   ○ Yes ○ No

9. Hoehn and Yahr stage I or II at Baseline.

   ○ Yes ○ No

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

    ○ Yes ○ No

11. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD LRRK2 or GBA Variant:

12. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

    ○ Yes ○ No

13. Hoehn and Yahr stage I or II at Baseline.

    ○ Yes ○ No

14. Confirmation of causative LRRK2 or GBA from the PPMI Screening Core.

    ○ Yes ○ No

15. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD SNCA or rare genetic variant such as Parkin or Pink1:

16. Confirmation of causative SNCA or rare genetic variant (such as Parkin or Pink1) from the PPMI Screening Core.

    ○ Yes ○ No

17. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

18. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic:

19. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

20. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic LRRK2:

21. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

22. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

23. Confirmation of causative LRRK2 from the PPMI Screening Core.

    ○ Yes ○ No

Exclusion Criteria – ALL PD Participants:

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).

   ○ No ○ Yes

2. A clinical diagnosis of dementia as determined by the investigator.

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

Additional Exclusion Criteria for Sporadic PD:

9. Receiving treatment for PD, including levodopa, dopamine agonists, MAO-B inhibitors, amantadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor), or Deep Brain Stimulation (DBS).

   ○ No ○ Yes

10. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

    ○ No ○ Yes

11. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

    ○ No ○ Yes

PPMI

Parkinson's Disease Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" for the applicable sections before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria – ALL PD Participants:

1. Male or female age 30 years or older at Screening Visit.

   ○ Yes ○ No

2. Has a clinical diagnosis of Parkinson's disease at Screening Visit.

   ○ Yes ○ No

3. Patients 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.

   ○ Yes ○ No

4. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

5. Able to provide informed consent.

   ○ Yes ○ No

6. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

7. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

Additional Inclusion Criteria for Sporadic PD:

8. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

   ○ Yes ○ No

9. Hoehn and Yahr stage I or II at Baseline.

   ○ Yes ○ No

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

    ○ Yes ○ No

11. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD LRRK2 or GBA Variant:

12. A diagnosis of Parkinson's disease for 2 years or less at Screening Visit.

    ○ Yes ○ No

13. Hoehn and Yahr stage I or II at Baseline.

    ○ Yes ○ No

14. Confirmation of causative LRRK2 or GBA from the PPMI Screening Core.

    ○ Yes ○ No

15. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD SNCA or rare genetic variant such as Parkin or Pink1:

16. Confirmation of causative SNCA or rare genetic variant (such as Parkin or Pink1) from the PPMI Screening Core.

    ○ Yes ○ No

17. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

18. Confirmation that participant is eligible to proceed to Baseline based on Screening SAA status (as determined by CSF, blood, skin, or other validated measure).

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic:

19. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

20. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

Additional Inclusion Criteria for PD Normosmic LRRK2:

21. A diagnosis of Parkinson's disease for 7 years or less at Screening Visit.

    ○ Yes ○ No

22. Hoehn and Yahr stage I, II, or III at Baseline.

    ○ Yes ○ No

23. Confirmation of causative LRRK2 from the PPMI Screening Core.

    ○ Yes ○ No

Exclusion Criteria – ALL PD Participants:

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).

   ○ No ○ Yes

2. A clinical diagnosis of dementia as determined by the investigator.

   ○ No ○ Yes

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

   ○ No ○ Yes

4. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

   ○ No ○ Yes

5. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

Additional Exclusion Criteria for Sporadic PD:

9. Receiving treatment for PD, including levodopa, dopamine agonists, MAO-B inhibitors, amandadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor), or Deep Brain Stimulation (DBS).

   ○ No ○ Yes

10. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

    ○ No ○ Yes

11. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

    ○ No ○ Yes

PPMI

Participant Global Impression (PGI)

Instructions: We are interested in collecting information about symptoms you may have been experiencing over the last 4 weeks.

Consider the **overall severity** of both your motor and non-motor symptoms. Examples of motor symptoms to think about are: tremor, stiffness, slowness, gait/balance, dyskinesias and "off" periods. Examples of non-motor symptoms to think about are: mood, anxiety, hallucinations, cognitive abilities, sleep and daytime sleepiness, fatigue, smell and taste, pain, urinary function, sexual function, and gastrointestinal function.

A. Assessment Date: __ __/__ __/ __ __ __ __ (mm/dd/yyyy)

1. Participant Assessment

Score	Overall signs & symptoms score
○ 0	Not assessed
○ 1	Normal (no signs or symptoms)
○ 2	Borderline
○ 3	Mild
○ 4	Moderate
○ 5	Marked
○ 6	Severe
○ 7	Very severe

PPMI

Participant Motor Function Questionnaire

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Who completed this questionnaire? ○ Participant ○ Caregiver ○ Participant and Caregiver

When answering these questions, please think about your current abilities.

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

PPMI

Participation in Other Studies Log

If Type of Research Study is "Investigational Clinical Trial", the Investigational Product (IP) should be recorded on the Concomitant Medication Log per the operations manual. If it is a blinded study and the drug is unknown, add as [study acronym] "study drug".

If the participant received a procedure as part of the study, be sure to record this on the Procedure for PD Log.

If the exact date of enrollment or conclusion of participation is unknown, please select the first of the month in the applicable month and year.

A. Site Aware Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Type of Research Study:

   ○ Investigational Clinical Trial

   ○ Observational or Other Clinical Research Study

   1a. Type of Investigational Clinical Trial:

      ○ Drug

      ○ Medical Device

      ○ Other Agent (such as imaging molecule)

      ○ Other, please specify: _____

2. Title of Research Study:

   ○ Slowing Parkinson's Early Through Exercise Dosage-Netherlands (Slow-SPEED-NL)

   ○ A 18-month Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of Oral UCB0599 in Study Participants With Early-stage Parkinson's Disease (ORCHESTRA)

   ○ Study in Parkinson's Disease of Exercise (SPARX3)

   ○ Consortium on Parkin/PINK1 (Parkin/PINK1)

   ○ Other, please specify: _____

3. Date of Enrollment: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

4. Date Participation Ended (If applicable): __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

PD Diagnosis History

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Date of first symptom onset (per the participant): __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
2. Date of Parkinson's disease diagnosis: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
3. Were the following symptoms present at the time of diagnosis:
   a. Resting Tremor ○ Yes ○ No ○ Unknown
   b. Rigidity ○ Yes ○ No ○ Unknown
   c. Bradykinesia ○ Yes ○ No ○ Unknown
   d. Postural instability ○ Yes ○ No ○ Unknown
   e. Other ○ Yes ○ No ○ Unknown
      i. If yes, please specify:

      _____

      _____
4. Side predominantly affected at onset: ○ Left ○ Right ○ Symmetric ○ Unknown

PPMI

Penn Parkinson's Daily Activities Questionnaire-27 (PDAQ-27)

Please check or fill in the following that best describes YOU. Please answer all questions. If you do not do an activity due to Parkinson's disease, please select "Cannot Do".

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. How much DIFFICULTY do you currently have reading the newspaper or magazine (not related to vision or motor symptoms)?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

2. How much DIFFICULTY do you currently have keeping track of time?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

3. How much DIFFICULTY do you currently have counting the correct amount of money when making purchases?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

4. How much DIFFICULTY do you currently have reading and following complex instructions (e.g., directions for a new medication)?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

5. How much DIFFICULTY do you currently have handling an unfamiliar problem?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

6. How much DIFFICULTY do you currently have explaining how to do something involving several steps to another person?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

7. How much DIFFICULTY do you currently have remembering a list of 4 or 5 errands without writing it down?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

8. How much DIFFICULTY do you currently have using a map to tell where to go?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

9. How much DIFFICULTY do you currently have remembering new information, like phone numbers or simple instructions?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

10. How much DIFFICULTY do you currently have doing more than one thing at a time?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

11. How much DIFFICULTY do you currently have learning to use new gadgets or machines around the house?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

12. How much DIFFICULTY do you currently have understanding your personal financial affairs?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

13. How much DIFFICULTY do you currently have maintaining or completing a train of thought?

   ○ None

   ○ A Little

   ○ Somewhat

   ○ A Lot

   ○ Cannot Do

14. How much DIFFICULTY do you currently have discussing a TV show, book, movie, or current events?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

15. How much DIFFICULTY do you currently have remembering what day and month it is?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

16. How much DIFFICULTY do you currently have carrying on a conversation with a small group of familiar people?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

17. How much DIFFICULTY do you currently have staying on topic while talking?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

18. How much DIFFICULTY do you currently have finding the right word?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

19. How much DIFFICULTY do you currently have getting things organized?
    - ○ None
    - ○ A Little
    - ○ Somewhat
    - ○ A Lot
    - ○ Cannot Do
20. How much DIFFICULTY do you currently have getting started on very simple tasks?
    - ○ None
    - ○ A Little
    - ○ Somewhat
    - ○ A Lot
    - ○ Cannot Do
21. How much DIFFICULTY do you currently have switching from one task to another?
    - ○ None
    - ○ A Little
    - ○ Somewhat
    - ○ A Lot
    - ○ Cannot Do
22. How much DIFFICULTY do you currently have remembering appointments?
    - ○ None
    - ○ A Little
    - ○ Somewhat
    - ○ A Lot
    - ○ Cannot Do
23. How much DIFFICULTY do you currently have accurately recalling conversations a few days later?
    - ○ None
    - ○ A Little
    - ○ Somewhat
    - ○ A Lot
    - ○ Cannot Do

24. How much DIFFICULTY do you currently have remembering things that have happened recently?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

25. How much DIFFICULTY do you currently have remembering where things are usually kept?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

26. How much DIFFICULTY do you currently have remembering the name of a familiar person (e.g. a family member or friend)?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

27. How much DIFFICULTY do you currently have finding your way around familiar places?

    ○ None

    ○ A Little

    ○ Somewhat

    ○ A Lot

    ○ Cannot Do

PPMI

Pregnancy Test

NOTE: If pregnant, consult protocol.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Is participant a female of childbearing potential?

○ Yes ○ No

1. If female of childbearing potential, was pregnancy test performed?

○ Yes ○ No

If no, explain why:

_____

_____

_____

1a. If pregnancy test performed, is the participant pregnant?

○ Yes ○ No

1b. Was the pregnancy test result confirmed prior to injection of the tracer?

○ Yes ○ No ○ Not Applicable

If no, explain why:

_____

_____

_____

PPMI

Primary Research Diagnosis

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Please select ONE answer below based on the Investigator's assessment of the research diagnosis of this participant:

1. Most likely primary diagnosis:
   - ○ Idiopathic PD
   - ○ Alzheimer's disease
   - ○ Frontotemporal dementia
   - ○ Corticobasal syndrome
   - ○ Dementia with Lewy bodies
   - ○ Dopa-responsive dystonia
   - ○ Essential tremor
   - ○ Hemiparkinson/hemiatrophy syndrome
   - ○ Juvenile autosomal recessive parkinsonism
   - ○ Motor neuron disease with parkinsonism
   - ○ Multiple system atrophy
   - ○ Neuroleptic-induced parkinsonism
   - ○ Normal pressure hydrocephalus
   - ○ Progressive supranuclear palsy
   - ○ Psychogenic parkinsonism
   - ○ Vascular parkinsonism
   - ○ No PD nor other neurological disorder
   - ○ Spinocerebellar Ataxia (SCA)
   - ○ Prodromal Synucleinopathy (e.g., RBD)
   - ○ Other neurological disorder(s),specify: _____

2. What is your percent confidence in your most likely primary diagnosis:
   - ○ 76-100%
   - ○ 51-75%
   - ○ 26-50%
   - ○ 0-25%

If diagnosis has changed since last visit, complete the following question:

3. The research diagnosis changed since the last vist. Please enter rationale to explain this new diagnosis:

_____

_____

_____

_____

PPMI

Procedure for PD Log

1. Date of Procedure: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)
2. Type of Procedure:
   - ○ DBS (Deep Brain Stimulation)
   - ○ Levodopa intestinal gel infusion
   - ○ High Intensity Focused Ultrasound (HiFU)
   - ○ Other, please specify: _____
   - ○ Unknown
3. Side:
   - ○ Bilateral
   - ○ Left
   - ○ Right
   - ○ Not Applicable (e.g., for levodopa intestinal gel infusion)
   - ○ Unknown
4. Location:
   - ○ GPi (Globus pallidus internal segment)
   - ○ STN (Subthalamic nucleus)
   - ○ Thalamus (VIM)
   - ○ Other, please specify: _____
   - ○ Not Applicable (e.g., for levodopa intestinal gel infusion)
   - ○ Unknown

PPMI

Prodromal Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria:

1. Confirmation that participant is eligible based on centrally determined criteria for the University of Pennsylvania Smell Identification Test (UPSIT) completed through other recruitment efforts.

   ○ Yes ○ No

2. Male or female age 40 years or older (except age 30 years or older for SNCA, or rare genetic variants (such as Parkin or Pink1) participants).

   ○ Yes ○ No

3. Individuals taking any of the following drugs: alpha methyldopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before SPECT imaging.

   ○ Yes ○ No

4. Able to provide informed consent.

   ○ Yes ○ No

5. Either is male, or is female and meets additional criteria below, as applicable:

   a. Female of childbearing potential who is not pregnant, lactating, or planning pregnancy during the study and has a negative pregnancy test on day of Baseline SPECT imaging test prior to injection of DaTscan™.

   ○ Yes ○ No

6. Confirmation that participant is eligible based on asyn SAA status (as determined by CSF, blood, skin, or other validated measure).

   ○ Yes ○ No

Exclusion Criteria:

1. Clinical diagnosis of PD, other parkinsonism, or dementia at screening.

   ○ No ○ Yes

2. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Baseline Visit.

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

6. Currently taking levodopa, dopamine agonists, MAO-B inhibitors, amantadine or another PD medication, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

   ○ No ○ Yes

7. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit, except for low-dose treatment of restless leg syndrome (with permission of medical monitor).

   ○ No ○ Yes

8. Any other reason that, in the opinion of the investigator, would render the participant unsuitable for study enrollment.

   ○ No ○ Yes

PPMI

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

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

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Information reported by:

○ Patient ○ Informant ○ Patient and Informant

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

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)?

   ○ No ○ Yes

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

   ○ No ○ Yes

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)?

   ○ No ○ Yes

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

   ○ No ○ Yes

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)?

   ○ No ○ Yes

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)?

   ○ No ○ Yes

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)?

   ○ No ○ Yes

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)?

   ○ No ○ Yes

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.)?

   ○ No ○ Yes

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

   ○ No ○ Yes

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

   ○ No ○ Yes

F. Medication Use

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

   ○ No ○ Yes ○ 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)?

   ○ No ○ Yes ○ Not Applicable

PPMI

REM Sleep Behavior Disorder Screening Questionnaire

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Source of information:

○ Participant ○ Caregiver ○ Participant and Caregiver

1.	I sometimes have very vivid dreams.	○ Yes	○ No
2.	My dreams frequently have an aggressive or action-packed content.	○ Yes	○ No
3.	The dream contents mostly match my nocturnal behavior.	○ Yes	○ No
4.	I know that my arms or legs move when I sleep.	○ Yes	○ No
5.	It thereby happened that I (almost) hurt my bed partner or myself.	○ Yes	○ No
6.	**I have or had the following phenomena during my dreams:**		
	6.1 speaking, shouting, swearing, laughing loudly	○ Yes	○ No
	6.2 sudden limb movements, “fights”.	○ Yes	○ No
	6.3 gestures, complex movements, that are useless during sleep, e.g., to wave, to salute, to frighten mosquitoes, fall off the bed.	○ Yes	○ No
	6.4 things that fell down around the bed, e.g., bedside lamp, book, glasses.	○ Yes	○ No
7.	It happens that my movements awake me.	○ Yes	○ No
8.	After awakening I mostly remember the content of my dreams well.	○ Yes	○ No
9.	My sleep is frequently disturbed.	○ Yes	○ No

Stiasny-Kolster, K et al. The REM Sleep Behavior Disorder Screening Questionnaire - A New Diagnostic Instrument. Movement Disorders.2007; 22(16):2386-2393.

10. **I have/had a disease of the nervous system:**

10.a	Stroke	○ Yes	○ No
10.b	Head trauma	○ Yes	○ No
10.c	Parkinsonism	○ Yes	○ No
10.d	Restless Leg Syndrome (RLS)	○ Yes	○ No
10.e	Narcolepsy	○ Yes	○ No
10.f	Depression	○ Yes	○ No
10.g	Epilepsy	○ Yes	○ No
10.h	Inflammatory disease of the brain	○ Yes	○ No
10.i	Other	○ Yes	○ No

Specify: _____

Stiasny-Kolster, K et al. The REM Sleep Behavior Disorder Screening Questionnaire - A New Diagnostic Instrument. Movement Disorders.2007; 22(16):2386-2393.

PPMI

Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following injection of the tracer, document this in the database within 24 hours of notification.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. This is a report of pregnancy for which person?

   ○ Female participant

   ○ Female partner of participant

2. Is the pregnancy confirmed as occurring within 30 days following the injection of the tracer?

   ○ No

   ○ Yes

   ○ Unknown

PPMI

Research Biospecimens

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Specimen Collection Kit Number (if any specimen collected or attempted):

__ __ __ __ __ __ __ (Seven alpha-numeric characters)

1. Fasting Status:

○ Fasted (Minimum of 8 hours) ○ Low Fat Diet ○ Not Fasted, No Low Fat Diet

1a. Date of last intake of food: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1b. Time of last intake of food: __ __:__ __ (24-hour clock)

2. Is the participant on medication for treating the symptoms of Parkinson's Disease?

○ No ○ Yes

2a. Date of most recent PD medication dosing: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

2b. Time of most recent/in-clinic PD medication dosing: __ __:__ __ (24-hour clock)

<u>Urine Sample Collection</u>

3. Urine for storage and analysis:

○ Not collected ○ Collected ○ Collected, unable to process/ship

3a. Date of urine sample collection: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

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

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

3d. Rate of centrifugation: _____ xg

3e. Duration of centrifugation: _____ minutes

3f. Temperature at which tube was spun: _____ ˚C

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

RNA - PAXgene Red Top

4. Blood for PAXgene/RNA:

○ Not collected ○ Collected ○ Collected, unable to process/ship

4a. Time of PAXgene/RNA sample collection: __ __:__ __ (24-hour clock)

4b. Total tube volume: _____ milliliters

4c. Date PAXgene/RNA samples placed in freezer: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

4d. Time PAXgene/RNA samples placed in freezer: __ __:__ __ (24-hour clock)

4e. Storage Temperature: _____ ˚C

Plasma - EDTA Purple Top

5. Blood for Plasma:

○ Not collected ○ Collected ○ Collected, unable to process/ship

5a. Time of plasma sample collection: __ __:__ __ (24-hour clock)

5b. Time of centrifugation: __ __:__ __ (24-hour clock)

5c. Rate of centrifugation: _____ xg

5d. Duration of centrifugation: _____ minutes

5e. Temperature at which tube was spun: _____ ˚C

5f. Total volume aliquoted after spinning: _____ milliliters

5g. Total number of aliquot tubes: _____

5h. Time plasma sample placed in freezer: __ __:__ __ (24-hour clock)

5i. Storage temperature: _____ ˚C

5j. Buffy coat:

○ Not collected ○ Collected ○ Collected, unable to process/ship

Serum - Red Top

6. Blood for Serum:

○ Not collected ○ Collected ○ Collected, unable to process/ship

6a. Time of serum sample collection: __ __:__ __ (24-hour clock)

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

6c. Rate of centrifugation: _____ xg

6d. Duration of centrifugation: _____ minutes

6e. Temperature at which tube was spun: _____ ˚C

6f. Total volume aliquoted after spinning: _____ milliliters

6g. Total number of aliquot tubes: _____

6h. Time serum sample placed in freezer: __ __:__ __ (24-hour clock)

6i. Storage temperature: _____ ˚C

Whole Blood - EDTA Purple Top

7. Whole blood collected:

○ Not collected ○ Collected ○ Collected, unable to process/ship

7a. Time of whole blood sample collection: __ __:__ __ (24-hour clock)

7b. Volume of blood collected: _____ milliliters

7c. Storage temperature: _____ ˚C

7d. Time of whole blood sample storage: __ __:__ __ (24-hour clock)

Blood Sample Collection

8. Date blood samples collected: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Research Proxy Designation

Please ensure the "Assessment Date" below reflects the date of research proxy identification, decline, change or withdrawal.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Does the participant want to identify or change a designated research proxy?
   - ○ Initial Identification
   - ○ Declined Research Proxy
   - ○ Changed Research Proxy
   - ○ Withdrew Research Proxy

PPMI

SCOPA-AUT

Assessment Date: __ __ /__ __/ __ __ __ __ (MM/dd/yyyy)

Source of Information:

○ Participant ○ Caregiver ○ Participant and Caregiver

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

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 selecting “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*

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

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

16. Have you fainted in the past 6 months?

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

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

    ○ never ○ sometimes ○ regularly ○ often

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

The following 3 questions are only for men

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

○ never ○ sometimes ○ regularly ○ often ○ *not applicable*

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

○ never ○ sometimes ○ regularly ○ often ○ *not applicable*

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

○ No ○ Yes: _____

The following 2 questions are only for women

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

○ never ○ sometimes ○ regularly ○ often ○ *not applicable*

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

○ never ○ sometimes ○ regularly ○ often ○ *not applicable*

The following questions are for everyone

The questions below are about the use of medication for which you may have or have not needed a doctor's prescription. If you use medication, also give the name of the substance.

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:

_____

_____

_____

PPMI

Screen Fail

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Participant did not enroll in PPMI Clinical due to:

   ○ Eligibility Criteria

   ○ Participant declined participation prior to completing baseline visit

   ○ Death

   1a. Please select the reason for declining:

      ○ Risks of protocol

      ○ Confidentiality issues

      ○ Protocol too time intensive

      ○ Changed mind about lumbar puncture

      ○ Travel requirements

      ○ Family or caregiver/informant advised declining

      ○ Physician (other than Site Investigator) advised declining

      ○ Enrolled in other study

      ○ No longer interested

      ○ Other

   1b. If applicable, date of death: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI

Skin Biopsy

Instructions: If only 1 biopsy can be collected, site should prioritize the frozen sample collection.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was skin biopsy completed?

   ○ No

   ○ Yes

   1a. If “no”, please specify reason below:

   ○ Participant declined biopsy

   ○ Procedure attempted unsuccessfully

   ○ Other

   If "Procedure attempted unsuccessfully" or "Other", please specify:

   _____

   _____

   _____

   1b. Specimen Collection Kit Number: __ __ __ __ __ __

2. Was lidocaine anesthesia administered?

   ○ No

   ○ Yes

   ○ Other anesthetic, please specify: _____

3. Was a formalin-fixed specimen collected?

○ No

○ Yes

3a. On which side of the body was the cervical paravertebral biopsy performed?

○ Right

○ Left

3b. What type of wound closure was used?

○ Dressing only

○ Steri strips

○ Suture

○ Other, specify: _____

3c. Time that biopsy was collected: __ __:__ __ (24-hour clock)

3d. Time biopsy specimen placed in formalin fixation: __ __:__ __ (24-hour clock)

3e. Formalin lot number: _____

4. Was a frozen specimen collected?

○ No

○ Yes

4a. On which side of the body was the cervical paravertebral biopsy performed?

○ Right

○ Left

4b. What type of wound closure was used?

○ Dressing only

○ Steri strips

○ Suture

○ Other, specify: _____

4c. Time that biopsy was collected: __ __:__ __ (24-hour clock)

4d. Time biopsy specimen was frozen at -80 ˚C: __ __:__ __ (24-hour clock)

PPMI

Socio-Economics

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Please record the participant's highest number of years of education completed: _____

PPMI

State-Trait Anxiety Inventory for Adults

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-1

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

2. I feel secure.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

3. I am tense.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

4. I feel strained.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

5. I feel at ease.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

6. I feel upset.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

7. I am presently worrying over possible misfortunes.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

8. I feel satisfied.

   ○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

9. I feel frightened.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

10. I feel comfortable.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

11. I feel self-confident.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

12. I feel nervous.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

13. I am jittery.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

14. I feel indecisive.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

15. I am relaxed.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

16. I feel content.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

17. I am worried.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

18. I feel confused.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

19. I feel steady.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

20. I feel pleasant.

○ 1 = Not at all ○ 2 = Somewhat ○ 3 = Moderately so ○ 4 = Very much so

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-2

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel.

21. I feel pleasant.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

22. I feel nervous and restless.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

23. I feel satisfied with myself.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

24. I wish I could be as happy as others seem to be.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

25. I feel like a failure.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

26. I feel rested.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

27. I am “calm, cool, and collected”.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

28. I feel that difficulties are piling up so that I cannot overcome them.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

29. I worry too much over something that really doesn’t matter.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

30. I am happy.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

31. I have disturbing thoughts.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

32. I lack self-confidence.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

33. I feel secure.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

34. I make decisions easily.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

35. I feel inadequate.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

36. I am content.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

37. Some unimportant thought runs through my mind and bothers me.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

38. I take disappointments so keenly that I can't put them out of my mind.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

39. I am a steady person.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

40. I get in a state of tension or turmoil as I think over my recent concerns and interests.

○ 1 = Almost never ○ 2 = Sometimes ○ 3 = Often ○ 4 = Almost always

PPMI

Symbol Digit Modalities Test

BL	MTH 12 V04	MTH 24 V06	MTH 36 V08	MTH 48 V10	MTH 60 V12	MTH 72 V13	MTH 84 V14	MTH 96 V15	MTH 108 V16	MTH 120 V17	MTH 132 V18	MTH 144 V19	MTH 156 V20
Form 1	Form 2	Form 1	Form 2	Form 1	Form 2	Form 1	Form 2	Form 1	Form 2	Form 1	Form 2	Form 1	Form 2

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Indicate the form version used at this visit: ○ Form 1 ○ Form 2

If form used is different than indicated in the protocol, comment below:

_____

_____

1. Total Correct (0-110): _____

PPMI

Trail Making A and B

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Part A

1. Did the participant complete the test within 150 seconds (maximum time)?

   ○ Yes ○ No

   1a. If yes, time to complete (in seconds): _____

   1b. If no, number correct: _____

Part B

2. Did the participant complete the test within 300 seconds (maximum time)?

   ○ Yes ○ No

   2a. If yes, time to complete (in seconds): _____

   2b. If no, number correct: _____

PPMI

University Of Pennsylvania Smell Identification Test (UPSIT)

Form Instructions

Only one answer choice should be selected for each question.

Note: Indication of the UPSIT version used is important in determining participant eligibility.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

B. Select below the version administered:

If the UPSIT envelope has "REVISED" printed in red on the front of the envelope, select "Revised" for the version.

○ Original ○ Revised

C. Select below the language the UPSIT was administered in:

☑

D. Is this participant a referral from the HeBA (Healthy Brain Aging) study?

○ Yes ○ No

Please refer to booklet 1 to enter responses for questions 1-10.

1. This odor smells most like:
   ○ A ○ B ○ C ○ D
2. This odor smells most like:
   ○ A ○ B ○ C ○ D
3. This odor smells most like:
   ○ A ○ B ○ C ○ D
4. This odor smells most like:
   ○ A ○ B ○ C ○ D
5. This odor smells most like:
   ○ A ○ B ○ C ○ D
6. This odor smells most like:
   ○ A ○ B ○ C ○ D
7. This odor smells most like:
   ○ A ○ B ○ C ○ D
8. This odor smells most like:
   ○ A ○ B ○ C ○ D
9. This odor smells most like:
   ○ A ○ B ○ C ○ D
10. This odor smells most like:
    ○ A ○ B ○ C ○ D

Please refer to booklet 2 to enter responses for questions 11-20.

11. This odor smells most like:
    ○ A ○ B ○ C ○ D
12. This odor smells most like:
    ○ A ○ B ○ C ○ D
13. This odor smells most like:
    ○ A ○ B ○ C ○ D
14. This odor smells most like:
    ○ A ○ B ○ C ○ D
15. This odor smells most like:
    ○ A ○ B ○ C ○ D
16. This odor smells most like:
    ○ A ○ B ○ C ○ D
17. This odor smells most like:
    ○ A ○ B ○ C ○ D
18. This odor smells most like:
    ○ A ○ B ○ C ○ D
19. This odor smells most like:
    ○ A ○ B ○ C ○ D
20. This odor smells most like:
    ○ A ○ B ○ C ○ D

Please refer to booklet 3 to enter responses for questions 21-30.

21. This odor smells most like:
    ○ A ○ B ○ C ○ D
22. This odor smells most like:
    ○ A ○ B ○ C ○ D
23. This odor smells most like:
    ○ A ○ B ○ C ○ D
24. This odor smells most like:
    ○ A ○ B ○ C ○ D
25. This odor smells most like:
    ○ A ○ B ○ C ○ D
26. This odor smells most like:
    ○ A ○ B ○ C ○ D
27. This odor smells most like:
    ○ A ○ B ○ C ○ D
28. This odor smells most like:
    ○ A ○ B ○ C ○ D
29. This odor smells most like:
    ○ A ○ B ○ C ○ D
30. This odor smells most like:
    ○ A ○ B ○ C ○ D

Please refer to booklet 4 to enter responses for questions 31-40.

31. This odor smells most like:
    ○ A ○ B ○ C ○ D
32. This odor smells most like:
    ○ A ○ B ○ C ○ D
33. This odor smells most like:
    ○ A ○ B ○ C ○ D
34. This odor smells most like:
    ○ A ○ B ○ C ○ D
35. This odor smells most like:
    ○ A ○ B ○ C ○ D
36. This odor smells most like:
    ○ A ○ B ○ C ○ D
37. This odor smells most like:
    ○ A ○ B ○ C ○ D
38. This odor smells most like:
    ○ A ○ B ○ C ○ D
39. This odor smells most like:
    ○ A ○ B ○ C ○ D
40. This odor smells most like:
    ○ A ○ B ○ C ○ D

PPMI

Visit Status

A. Date of last assessment: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Indicate how this visit was conducted:

   ○ In Clinic Visit

   ○ Remote Visit

   ○ Out of Clinic Visit

   1a. Indicate primary reason Out of Clinic visit was conducted:

      ○ PD too advanced

      ○ Due to other illness

      ○ Family, Caregiver, or social issues

      ○ Participant moved

      ○ Transportation/Travel issues

      ○ Hospitalized/Institutionalized

      ○ Subject refused site visit

      ○ Participant concern due to COVID-19

      ○ Governmental restrictions due to COVID-19

      ○ Site restrictions due to COVID-19

PPMI

Vital Signs

Weight and Height should be completed at Baseline and annual visits only.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Weight: _____ kg
2. Height: _____ cm
3. Temperature: _____ ˚C
4. Arm used to measure blood pressure: ○ Right arm ○ Left arm

To be taken after participant has been supine for 1-3 minutes:

5. Supine blood pressure: _____ / _____ mmHg (systolic/diastolic)
6. Supine heart rate: _____ beats per minute

To be taken after participant has been standing for 1-3 minutes:

7. Standing blood pressure: _____ / _____ mmHg (systolic/diastolic)
8. Standing heart rate: _____ beats per minute