PPMI

ADVERSE EVENT LOG

Instructions: Assess for adverse events (observed, elicited from, or volunteered by the participant) at visits when SPECT 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.

AE #	Adverse Event	Start Date (mm/dd/yyyy)	Stop Date (mm/dd/yyyy)	Severity 1=mild 2=moderate 3=severe	Serious 0=no 1=yes	Relationship to Study 1 =unrelated 2=unlikely 3=possible 4=probably 5=definite	How is it related 1 =DaTscan 2 = LP 3=skin biopsy 4 = AV-133 5 = MK-6240 PET Scan	Resulted in withdrawal from study 0=no 1=yes	Complete when resolved (or up to 30 days post-procedure) Primary Outcome 1=recovered 2=under treatment/observation 3=change in AE characteristic 4=sequela 5=fatal 6=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 SPECT imaging procedure to assess for adverse events.

1. Was an LP, skin biopsy or DaTscan imaging scan conducted at this visit? **YES** **NO**

If no, question 2 does not require completion.

2. Was contact made during this telephone call? **YES** **NO**
   a. If no, indicate the reason:
      1 = phone disconnected/number no longer in service
      2 = messages for participant were not returned
      3 = participant moved/unable to locate
      4 = other, please specify:

      _____

      _____

If no, question 3 does not require completion.

3. Where any adverse events reported by the participant? **YES** **NO**

If yes, new adverse event(s) should be documented on the Adverse Event Log.

PPMI
CLINICAL LABS

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

Comments:

_____

_____

_____

PPMI
Conclusion of Study Participation

1. Date of conclusion of participation _____

2. Please select a reason for conclusion of study participation:

   01 = Completed study per protocol

   02 = Transportation/Travel issues (ex: logistics or travel, moved away from study site)

   03 = Burden of study procedures (other than travel)

   04 = Family, care-partner, or social issues

   05 = Non-compliance with study procedures

   06 = Adverse event

   07 = Death

   08 = Other, please specify:

_____

_____

_____

_____

3. Did increasing PD disability contribute to the decision to withdraw from PPMI 2.0?

   YES NO

PPMI
Concomitant Medication Log

Row	Medication Name (generic preferred)	Start Date	Stop Date	Indication (See options below)

Indication Selections*:
Anxiety
Atrial Fibrilation/Arrhythmias
Benign Prostatic hypertrophy/overactive bladder
Cognitive dysfunction
Congestive heart failure
Constipation
Coronary artery disease, peripheral artery disease, stroke
Daytime sleepiness
Delusions, hallucinations, psychosis
Depression
Diabetes
GERD
Hyperlipidemia
Hypertension
Insomnia
Nausea
Pain
REM-behavior disorder
Restless Leg syndrome
Sexual dysfunction
Sialorrhea/drooling
Supplements/homeopathic medication
Thyroid disorder
Vitamins/coenzymes
Other, please specify: _____

**Only above options will be available in EDC*

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, or may withdraw consent given previously.

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

   YES **NO**

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

   If no to Q1, skip Q2.

2. Participant or research proxy confirmed willingness for continued participation in PPMI Clinical optional activities (e.g., sharing of contact info, future contact by study team)?

   YES **NO**

   If no, update the Informed Consent Tracking Log.

Comment:

PPMI

DaTscan IMAGING

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

1. DaTscan imaging scan:

   0 = Not Completed

   1 = Completed at this visit

   2 = Completed using a previously acquired DaTscan *(i.e., acquired prior to participant's consent to PPMI)*

      1a. If using a previously acquired DaTscan, provide date of scan: ____ / ____ / _____

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

   If not completed, provide reason:

   _____

   _____

   _____

   _____

PPMI
DEMOGRAPHICS

1. Handedness:
   1 = Right
   2 = Left
   3 = Mixed

2. Does participant identify their ethnicity as being Hispanic or Latino (Spanish origin)? (**0 = No, 1 = Yes, 2 = Unknown or not reported)**

3. Does participant identify as being of Ashkenazi Jewish descent? (**0 = No, 1 = Yes, 2 = Unknown or not reported)**

4. Does participant identify as being of Basque descent? (**0 = No, 1 = Yes, 2 = Unknown or not reported**)

5. Does the participant identify as being of African Berber descent? (**0 = No, 1 = Yes, 2 = Unknown or not reported**)

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

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

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

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

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

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

    _____

    _____

PPMI

DOCUMENTATION OF INFORMED CONSENT

Instruction: Document date participant signed consent as the "Assessment Date" above.

#1-8 MUST = Yes in order to consent to participation in PPMI Clinical.

1. Informed consent was discussed with participant and/or legally authorized representative for the PPMI Clinical study. **YES NO**

2. Consent form was provided to the participant and/or legally authorized representative for review. **YES NO**

3. Participant and/or legally authorized representative were given adequate time to read the consent form and discuss the study with study staff and/or person of participant's choice. **YES NO**

4. Participant and/or legally authorized representative signed and dated the informed consent. **YES NO**

5. Copy of the consent form was provided to the participant and/or legally authorized representative upon conclusion of the consent process. **YES NO**

6. Consent has been signed prior to any study procedures being performed. **YES NO**

7. Informed consent obtained by person authorized on site delegation log. **YES NO**

8. During the informed consent process, the participant and/or authorized representative had the opportunity to ask questions and receive answers by study personnel. **YES NO**

9. Comments (if any of the above steps were not completed, note below, including corrective action if applicable)
   this must be completed if any questions 1-8 not selected "yes".

_____

_____

_____

_____

PPMI

EPWORTH SLEEPINESS SCALE

A. Source of Information: 1 = Participant, 2 = Caregiver/Informant, 3 = Participant and Caregiver/Informant ☐

How likely are you to doze off or fall asleep in situations described below, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you haven't done some of these things recently try to work out how they would have affected you. Use the following scale to choose the **most appropriate number** for each situation:

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

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

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

PPMI

FAMILY HISTORY

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

   Yes No

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.

	Number of Family Members	Number with PD or Parkinsonism
Biological Mother	1	
Biological Father	1	
Full Brothers		
Full Sisters		
Maternal Half Siblings		
Paternal Half Siblings		
Maternal Grandmother	1	
Maternal Grandfather	1	
Paternal Grandmother	1	
Paternal Grandfather	1	
Maternal Aunts and Uncles		
Paternal Aunts and Uncles		
Maternal Cousins		
Paternal Cousins		
Children		

2. Do you have a more distant relative not listed above who has/had Parkinson's disease or Parkinsonism? **Yes** **No**

PPMI
Features of Parkinsonism

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
   Yes **No** **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
   Yes **No** **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
   Yes **No** **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
   Yes **No** **uncertain**

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

   1 = Abnormalities that are signs of PS (90 - 100%)
   2 = Abnormalities that are likely signs of PS (70 - 89%)
   3 = Abnormalities that may be signs of PS (50 - 69%)
   4 = Non-specific abnormalities (25 - 49%)
   5 = No evidence of parkinsonian signs (0 - 24%)

PPMI

FREEZING AND FALLS

A. Indicate the source of information:

1 = Participant 2 = Caregiver/Informant 3 = Participant and Caregiver/Informant

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 on 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 on average of once daily

4 = Falls more than once daily

Instructions to Match EDC dynamic functionality:
If the participant responded options 3-4 to question #1, complete questions #5-6.
If the participant responded options 1-4 to question #2, complete questions #5-6.
If the participant responded options 3-4 to question #3, complete questions #5-6.
If the participant responded options 1-4 to question #4, complete questions #5-6.

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

5a. Fracture of the hip or lower limb	**YES**	**NO**
5b. Fracture of upper extremity	**YES**	**NO**
5c. Skull fracture	**YES**	**NO**
5d. Other fracture	**YES**	**NO**

If yes, please specify: _____

5e. Head injury without loss of consciousness	**YES**	**NO**
5f. Head injury with loss of consciousness	**YES**	**NO**
5g. Laceration requiring sutures (stitches)	**YES**	**NO**
5e. Other	**YES**	**NO**

If yes, please specify: _____

6. Did any of these falls result in:

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

PPMI

GENERAL PHYSICAL EXAM

Organ system abnormalities by examination:

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:

Specify and describe briefly:

PPMI

GERIATIRIC DEPRESSION SCALE-15

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

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

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.

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 DaTscan imaging.

   YES NO

3. Confirmation that participant is eligible based on Screening DaTscan 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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.

   YES NO

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

   YES NO

PPMI

Informed Consent Tracking Log

Study Template Version Date	Site Version Date	Site IRB Approval Date	Date ICF Signed	Reason for Consent	Consent to share contact info with FOUND Y/N	Consent to share contact info with Pathology Core Y/N/NA	Consent to re-contact for use of information Y/N	Consent to re-contact for other research Y/N	Comment

PPMI
LEDD Concomitant Medication Log

Row	Medication Name (generic preferred)	Dose Strength	Units	Dose taken (1 tab, 2 tab etc)	Dose frequency per day (numeric only- do not use TID, etc)	Start Date	Stop Date

PPMI
Lumbar Puncture

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

1. Was the lumbar puncture for collection of CSF completed?
   0 = Not Done, 1 = Collected, 2 = Partial Collection, 3 = Attempted, no collection

   If Q1 = 0, 2 or 3, answer Q2.
2. Indicate primary reason for issues with CSF collection:
   1=Participant refused
   2=Participant not feeling well enough to attempt
   3=Site issues (e.g., scheduling difficulties on site end)
   4=History of difficulty obtaining LP (e.g., participant unable to tolerate procedure in the past; adverse events associated with prior lumbar punctures)
   5=Spinal issues (e.g., recent back surgery, spinal stenosis, etc.)
   6=Medical contraindications to lumbar puncture (e.g., started anticoagulants, lab results, altered mentation, focal neurologic signs, papilledema, seizures, tumor)
   7=Other, specify in comments

   If Q1 = 0 no more responses required.

3. Date of last intake of food:

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

5. Fasting status:
   a. 1 = Fasted (minimum of 8 hours), 2 = Low-Fat Diet, 3 = Not Fasted, No Low-Fat Diet
6. Is the participant on medication for treating the symptoms of Parkinson's disease?
   1= Yes
   2 = No

   6a. Date of most recent PD medication dosing: *date field free text in MM/DD/YYY format*
   6b. Time of most recent/in clinic PD medication dosing: *free test field to enter numbers HH:MM format:*

7. Indicate needle used to collect CSF:
   1 = 20g Quincke (sharp bevelled) needle
   2 = 22g Quincke (sharp bevelled) needle
   3 = 25g Quincke (sharp bevelled) needle
   4 = 22g Sprotte (atraumatic) needle
   5 = 24g Sprotte (atraumatic) needle (preferred)

6 = 18g
7 = Other, specify in comments

8. Indicate method used to collect CSF:
   1 = Gravity
   2 = Syringe suction

9. Indicate location where LP performed:
   0 = L2-L3 Interspace
   1 = L3-L4 Interspace
   2 = L4-L5 Interspace
   3 = L5-S1 Interspace
   4 = Unknown

10. Position of participant when lumbar puncture performed:
    1 = Sitting, leaned over (preferred)
    2 = Lying, curled up on side
    3 = Prone
    4 = Unknown
    5 = Other, specify in comments

11. Time CSF collection completed: (24-hour clock)

12. Volume of CSF collected prior 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: (Celsius)

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? (0 = No, 1 = Yes)

20. Indicate how samples stored: (1 = freezer, 2 = placed on dry ice)

If response = 1, complete Qa.

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

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? (0 = No, 1 = Yes, 2 = Site exemption)
If No, specify in Comments.
If response = Yes, Questions 23-26 required.

23. What is the white blood cell count (**Units should be per cubic microliter**)?

24. What is the red blood cell count (**Units should be per cubic microliter**)?

25. What is the total protein (**Units should be mg/dL**)?

26. What is the total glucose (**Units should be mg/dL**)?

27. Was a fluoroscopy performed? (0 = No, 1 =Yes)
If response = Yes, Question a required.
a. Date of fluoroscopy:

28. Was a lumbar spine film performed? (0 = No, 1 =Yes)
If response = Yes, Question a required.
a. Date of spine film:

If Q27 or Q28 = Yes, Question 29 is required.

29. Indicate reason for use of additional guidance:
1=Previously failed attempt
2=Uncertain about location
3=Part of standard procedure
4=Other

PPMI
MEDICAL CONDITIONS LOG

KEY for CATEGORY:

1d = Dermatological
1e Ophthalmological
1f = ENT
1g = Pulmonary
1h Cardiovascular
1i Gastrointestinal
1j =Hepatobiliary
1k = Renal
1l =Gynecological/Urologic
1m = Musculoskeletal
1n =Metabolic/Endocrine
1o = Hemato/Lymphatic
1p = Neurologic (other than disease under study)
1q = Psychiatric
1r = Allergy/Immunologic – Please note drug allergies
1s = Other
1t = COVID-19 (SARS-CoV-2)

Row #	Category (See KEY above)	Date of Diagnosis (MM/DD/YY YY)	Enter diagnosed medical conditions. Specify the disorder/diagnosis and use only one line per description. **DO NOT ABBREVIATE.**	Resolved 0 = No 1 = Yes	Date of Resolution (MM/DD/YYYY)

PPMI

MAGNETIC RESONANCE IMAGING

1. MRI scan:

   1 = Completed

   0 = Not Completed

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

   0 = No
   1 = Yes

   2a. Date of last dose prior to scan: ____ / ____ / ____

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

   If MRI not completed, provide reason:

   _____

   _____

   _____

   _____

PPMI

MODIFIED SCHWAB & ENGLAND ACTIVITIES OF DAILY LIVING

Please provide assessment 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.
90%	Completely independent. Able to do all chores with some degree of slowness, difficulty and impairment. Might take twice as long. Beginning to be aware of difficulty.
80%	Completely independent in most chores. Takes twice as long. Conscious of difficulty and slowness.
70%	Not completely independent. More difficulty with some chores. Three to four times as long in some. Must spend a large part of the day with chores.
60%	Some dependency. Can do most chores, but exceedingly slowly and with much effort. Errors; some impossible.
50%	More dependent. Help with half, slower, etc. Difficulty with everything.
40%	Very dependent. Can assist with all chores but few alone.
30%	With effort, now and then does a few chores alone or begins alone. Much help needed.
20%	Nothing alone. Can be a slight help with some chores. Severe invalid.
10%	Totally dependent, helpless. Complete invalid.
0%	Vegetative functions such as swallowing, bladder, and bowel functions are not functioning. Bedridden.

Consensus Rating Percent: **_____ %**
(Investigator, participant, caregiver/informant)

PPMI

Neurological Exam

Answers should be selected by checking the appropriate box. Only one response choice allowed per item.

Mental Status

- ☐ Normal
- ☐ Abnormal (specify: _____)
- ☐ Not tested
- ☐ Unable to test

Cranial Nerves (II –XII)

- ☐ Normal
- ☐ Abnormal (specify: _____)
- ☐ Not tested
- ☐ Unable to test

Motor exam (other than PD)

- ☐ Normal
- ☐ Abnormal (specify: _____)
- ☐ Not tested
- ☐ Unable to test

Sensory exam

- ☐ Normal
- ☐ Abnormal (specify: _____)
- ☐ Not tested
- ☐ Unable to test

Coordination (other than PD)

- ☐ Normal
- ☐ Abnormal (specify: _____)
- ☐ Not tested

☐ Unable to test

Reflexes

☐ Normal
☐ Abnormal (specify: _____)
☐ Not tested
☐ Unable to test

Gait (other than PD)

☐ Normal
☐ Abnormal (specify: _____)
☐ Not tested
☐ Unable to test

PPMI

NEURO-QoL COGNITIVE FUNCTION SHORT FORM

Cognition Function– Short Form

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

	How much DIFFICULTY do you currently have…	**None**	**A little**	**Somewhat**	**A lot**	**Cannot do**
NQCOG22v1	reading and following complex instructions (e.g., directions for a new medication)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG24v1	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)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG25v1	managing your time to do most of your daily activities?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG40v1	learning new tasks or instructions?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

English
March 6, 2014

PPMI

NEURO-QoL COMMUNICATION SHORT FORM

PPMI 207

Neuro QOL

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

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

Neuro-QOL Scale v1.0 – Communication – Short Form

Communication – Short Form

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

	How much DIFFICULTY do you currently have…	None	A little	Somewhat	A lot	Cannot do
NQCOG01	writing notes to yourself, such as appointments or 'to do' lists?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG04	understanding family and friends on the phone?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG08	carrying on a conversation with a small group of familiar people (e.g., family or a few friends)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG10	organizing what you want to say?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG11	speaking clearly enough to use the telephone?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

English
March 6, 2014

PPMI

NEURO-QoL LEF MOBILITY SHORT FORM

Lower Extremity Function (Mobility) – Short Form

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

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
NQMOB37	Are you able to get on and off the toilet?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB30	Are you able to step up and down curbs?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB26	Are you able to get in and out of a car?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB32	Are you able to get out of bed into a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB25	Are you able to push open a heavy door?..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB33	Are you able to run errands and shop?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB31	Are you able to get up off the floor from lying on your back without help?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB28	Are you able to go for a walk of at least 15 minutes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

English
March 6, 2014

PPMI

NEURO-QoL UEF FINE MOTOR ADLT SHORT FORM

Upper Extremity Function (Fine Motor, ADL) – Short Form

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

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
NQUEX29	Are you able to turn a key in a lock?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX20	Are you able to brush your teeth?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX44	Are you able to make a phone call using a touch tone key-pad?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX36	Are you able to pick up coins from a table top?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX30	Are you able to write with a pen or pencil?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX28	Are you able to open and close a zipper?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX33	Are you able to wash and dry your body?..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQUEX37	Are you able to shampoo your hair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

English
March 6, 2014

PPMI
OTHER CLINICAL FEATURES

Other features supportive of Parkinson's disease

1.	Stooped posture	Yes	No	uncertain
2.	Decreased arm swing	Yes	No	uncertain
3.	Shuffling gait	Yes	No	uncertain
4.	Micrographia	Yes	No	uncertain
5.	Diminished olfaction	Yes	No	uncertain
6.	Seborrheic dermatitis	Yes	No	uncertain
7.	Dream enactment suggestive of REM sleep behavior disorder	Yes	No	uncertain

Atypical motor features

1.	Postural instability or gait freezing in the first 3 years	Yes	No	uncertain
2.	Supranuclear gaze palsy	Yes	No	uncertain
3.	Dysphagia	Yes	No	uncertain
4.	Dysarthria	Yes	No	uncertain
5.	Inspiratory stridor	Yes	No	uncertain
6.	Disproportionate anterocollis	Yes	No	uncertain
7.	Wide based gait / cerebellar features	Yes	No	uncertain
8.	Myoclonous	Yes	No	uncertain
9.	Dystonia	Yes	No	uncertain
10.	Prominent action tremor	Yes	No	uncertain

Neurobehavioral features

1.	Cognitive fluctuations	Yes	No	uncertain
2.	Systematized delusions or visual hallucinations unrelated to medications	Yes	No	uncertain
3.	Depression	Yes	No	uncertain
4.	Anxiety	Yes	No	uncertain
5.	Apathy	Yes	No	uncertain

Other non-motor features associated with atypical parkinsonism

1.	Symptomatic dysautonomia unrelated to medications, including:			
	1a. postural hypotension	Yes	No	uncertain
	1b. sexual dysfunction	Yes	No	uncertain
	1c. urinary dysfunction	Yes	No	uncertain
	1d. bowel dysfunction	Yes	No	uncertain
2.	Unequivocal cortical sensory loss (i.e., graphesthesia, stereognosis with intact primary sensory modalities)	Yes	No	uncertain
3.	Limb ideomotor apraxia	Yes	No	uncertain
4.	Otherwise unexplained pyramidal tract signs	Yes	No	uncertain
5.	Alien limb phenomenon	Yes	No	uncertain
6.	Definite response to alcohol	Yes	No	uncertain

Response to therapy

1.	Clear and dramatic response to levodopa	Yes	No	N/A
2.	Little or no response to levodopa	Yes	No	N/A
3.	Neuroleptic super-sensitivity	Yes	No	N/A
4.	Motor fluctuations	Yes	No	N/A
5.	Dyskinesia	Yes	No	N/A

PPMI

PARTICIPANT MOTOR FUNCTION QUESTIONNAIRE

A. Who completed this questionnaire?

1 = participant 2 = caregiver 3 = Participant and Caregiver

When answering these questions, please think about your current abilities.

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

PPMI

PD DIAGNOSIS HISTORY

1. Date of first symptom onset (per the participant): _____ /_____ /_____
2. Date of Parkinson's disease diagnosis: _____ /_____ /_____
3. Were the following symptoms present at the time of diagnosis:
    a. Rigidity **YES** **NO** **UNKNOWN**
    b. Bradykinesia **YES** **NO** **UNKNOWN**
    c. Postural instability **YES** **NO** **UNKNOWN**
    d. Other **YES** **NO** **UNKNOWN**
        i. If yes, please specify:

        _____

        _____
4. Side predominantly affected at onset:

LEFT **RIGHT** **SYMMETRIC** **UNKNOWN**

PPMI

Parkinson's Disease 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

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

   YES NO

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

   YES NO

4. 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

5. Hoehn and Yahr stage I or II at Baseline.

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.
   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

2. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit.

   YES NO

3. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

   YES NO

4. 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).

   YES NO

5. A clinical diagnosis of dementia as determined by the investigator.

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

    YES NO

PPMI

Parkinson's Disease-LRRK2 or GBA 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

2. A diagnosis of Parkinson disease for 2 years or less 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. Hoehn and Yahr stage I or II at Baseline.

   YES NO

5. Confirmation of causative LRRK2 or GBA (willingness to undergo genetic testing as part of genetic screening and be informed of genetic testing results, or documentation of prior genetic testing results).

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.
   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

PPMI

Parkinson's Disease-SNCA or rare genetic variant 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

2. Parkinson disease diagnosis 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. Hoehn and Yahr stage I, II, or III at Baseline.

   YES NO

5. Confirmation of causative SNCA or Parkin mutation (willingness to undergo genetic testing as part of genetic screening and be informed of genetic testing results, or approved documentation of prior genetic testing results).

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.

   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

PPMI

PREGNANCY TEST

A. Is participant of childbearing potential?

YES **NO**

1. If female of childbearing potential, was pregnancy test performed?

YES **NO**
If no, specify in comments below

1a. If response to question 1 is “yes”, is the participant pregnant?

YES **NO**

1b. Was the pregnancy test result confirmed prior to DaTscan injection for SPECT scan?

YES **NO**

NOTE: If pregnant, consult protocol.

Comments:

_____

_____

_____

_____

PPMI
Primary Clinical Diagnosis

Please select ONE answer below:

1. Most likely primary diagnosis:

01 = Idiopathic PD

02 = Alzheimer's disease

03 = Frontotemporal dementia

04 = Corticobasal syndrome

05 = Dementia with Lewy bodies

06 = Dopa-responsive dystonia

07 = Essential tremor

08 = Hemiparkinson/hemiatrophy syndrome

09 = Juvenile autosomal recessive parkinsonism

10 = Motor neuron disease with parkinsonism

11 = Multiple system atrophy

12 = Neuroleptic-induced parkinsonism

13 = Normal pressure hydrocephalus

14 = Progressive supranuclear palsy

15 = Psychogenic parkinsonism

16 = Vascular parkinsonism

17 = No PD nor other neurological disorder

18 = Spinocerebellar Ataxia (SCA)

97 = Other neurological disorder(s) (specify)_____

2. What is your percent confidence in your most likely primary diagnosis:
   1. 76-100%
   2. 51-75%
   3. 26-50%
   4. 0-25%

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.

Inclusion Criteria:

1. Enrolled in PPMI 2.0 Remote and based on risk criteria, or olfaction, and/or other PD assessments in the PPMI 2.0 Remote protocol are eligible for PPMI 2.0 Clinical.

   YES NO
2. Male or female age 60 years or older (except age 30 years or older for SNCA, or rare genetic mutations (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 DaTscan imaging.

   YES NO
4. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO
5. Able to provide informed consent.

   YES NO
6. Women may not be pregnant, lactating or planning pregnancy during the study.

   (Includes a negative pregnancy test on day of Screening DaTscan imaging test prior to injection of DaTscan.)

   YES NO

Exclusion Criteria:

1. Clinical diagnosis of PD, other parkinsonism, or dementia.

   YES NO
2. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening Visit.

   YES NO
3. Current treatment with anticoagulants (e.g. coumadin, heparin) that might preclude safe completion of the lumbar puncture.

   YES NO

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.

   YES NO

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

   YES NO

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

Reported : _____Patient _____Informant* _____Patient and Informant

Patient name: _____

Date: _____

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

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

A. GAMBLING

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

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

B. SEX

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

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

C. BUYING

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

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

____Yes____No

D. EATING

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

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

E. OTHER BEHAVIORS

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

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

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

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

F. MEDICATION USE

1. Do you or others (including your physicians) think that you consistently take too much of your Parkinson's medications? ____Yes____No____Not applicable

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

PPMI

REM SLEEP BEHAVIOR DISORDER SCREENING QUESTIONNAIRE (RBDSQ)

A. Source of information:

Participant **Caregiver/Informant** **Participant and Caregiver/Informant**

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 by 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 of 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**
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	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, specify: _____		

PPMI

REPORT OF PREGNANCY

Note: If a pregnancy was confirmed as occurring within 30 days following DaTscanTM injection, document this in the database within 24 hours of notification.

1. This is a report of pregnancy for which person?

   1 = Female participant

   2 = Female partner of male participant

2. Is the pregnancy confirmed as occurring within 30 days following the DaTscan injection?

   0 = No

   1 = Yes

   2 = Unknown

PPMI

RESEARCH BIOSPECIMENS

1. Fasting Status:
   1 = Fasted (Minimum of 8 hours)
   2 = Low Fat Diet
   3 = Not Fasted, Not Low-Fat Diet

   1a. Date of Last intake of food (MM/DD/YYY)
   1b. Time of last intake of food (24-hour clock)

2. Is the participant on medication for treating the symptoms of Parkinson's Disease?
   1 = Yes
   0 = No

   2a. Date of most recent PD medication dosing (MM/DD/YYYY)
   2b. Time of most recent/in-clinic PD medication dosing (24-hour clock)

Urine Sample Collection

3. Urine for storage and analysis (1 = collected, 0 = not collected)
   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 (Celsius)
   3g. Time urine sample placed in freezer (24-hour clock)

RNA-Paxgene RED TOP

4. Blood for Paxgene/RNA (1 = collected, 0 = not collected)
   5a. Time of PAXgene/RNA sample collections (24-hour clock)
   5b. Date PAXgene/RNA samples placed in freezer (MM/DD/YYYY)
   5c. Time PAXgene/RNA samples placed in freezer (24-hour clock)
   5d. Storage Temperature (Celsius)

Plasma- EDTA Purple Top

5. Blood for Plasma (1 = collected, 0 = not collected)
   6a. Time of plasma 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 (Celsius)
6f. Total volume aliquoted after spinning (millimeters)
6g. Total number of aliquot tubes
6h. Time plasma sample placed in freezer (24-hour clock)
6i. Storage temperature: (Celsius)
6j. Buffy coat: (1 = collected, 0 = not collected)

Serum- RED TOP

6. Blood for Serum (1 = collected, 0 = not collected)
   7a. Time of serum sample collection (24-hour clock)
   7b. Time of centrifugation (24-hour clock)
   7c. Rate of centrifugation (xg)
   7d. Duration of Centrifugation (minutes)
   7e. Temperature at which tube was spun (Celsius)
   7f. Total volume aliquoted after spinning (milliliters)
   7g. Total number of aliquot tubes:
   7h. Time serum sample placed in freezer (24-hour clock)
   7i. Storage temperature (Celsius)

Whole Blood- EDTA Purple Top

7. Whole blood collected (1 = collected, 0 = not collected
   8a. Time of whole blood sample collection (24-hour clock)
   8b. Volume of blood collected (milliliters)
   8c. Storage temperature (Celsius)

Blood Sample Collection

8. Date blood samples collected (MM/DD/YYYY)

PPMI

SOCIO-ECONOMICS

1. Please record the participant's highest number of years of education completed: _____

   Response should be a numeric entry answer; maximum allowable answer is 35 years.

PPMI

SCREEN FAIL

1. Participant did not enroll in PPMI Clinical due to:

   1 = Eligibility Criteria

   2 = Participant declined participation prior to completing baseline visit

   If option 2 is selected, complete Q1a.

   a. Please select the reason for declining:

      1 = Risks of protocol

      2 = Confidentiality issues

      3 = Protocol too time intensive

      4 = Changed mind about lumbar puncture

      5 = Travel requirements

      6 = Family or caregiver/informant advised declining

      7 = Physician (other than Site Investigator) advised declining

      8 = Enrolled in other study

      9 = No longer interested

      99 = Other

PPMI Skin Biopsy

1. Was skin biopsy completed? (0 = No, 1 = Yes)

   1a. If "no", please specify reason below:

   1 = Participant declined biopsy

   2 = Procedure attempted unsuccessfully, please specify: _____

   3 = Other, specify: _____

2. Was lidocaine anesthesia administered? (0 = No, 1 = Yes, 2 = other anesthetic, please specify _____)

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

4. What type of wound closure was used?

   1 = dressing only
   2 = steri strips
   3 = suture
   4 = other (specify) _____

5. Time that biopsy was collected: (24-hour clock)

6. Time biopsy specimen placed in formalin fixation: (24-hour clock)

7. Formalin lot number: _____

PPMI

SURGERY FOR PD LOG

Date of Surgery	Type of Surgery	Side	Location (Choose all that apply)

"Type of Surgery"
01 = Deep Brain Stimulation (DBS)
02 = Levodopa intestinal gel infusion
03 = Focused Ultrasound
04 = Other, please specify
05 = Unknown

"Side"
01 = Bilateral
02 = Left
03 = Right
04 = Not Applicable (e.g., for levodopa intestinal gel infusion)
05 = Unknown

"Location"
01 = GPi (Globus pallidus internal segment)
02 = STN (subthalmic nucleaus)
03 = Other, please specify
04 = Not Applicable (e.g., for levodopa intestinal gel infusion)
05 = Unknown

*Only above options will be available in EDC

PPMI

MDS-UPDRS Part III ON/OFF Determination & Dosing

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.

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

Yes **No**

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

Yes **No**

*If **NO to Q1 and Q2** → form is complete and complete one, untreated MDS-UPDRS part III CRF in visit.*

*If **YES to Q1 and/or Q2** → complete question 3 and dosing Information section, and complete "ON MDS-UPDRS Part III" CRF and "OFF MDS-UPDRS Part III":*

3. Will the first MDS-UPDRS Part III be an "ON" or "OFF" examination?

On Off

MDS-UPDRS Dosing Information

For the OFF MDS-UPDRS Part III:

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

   Yes **No**

5. If no, please select the reason:

   1 = Disease severity preventing participant from staying off medications/turning off DBS

   2 = Participant did not bring medication to clinic to turn ON

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

   4 = Participant does not feel comfortable turning off DBS

   5 = Participant/Site forgot to turn off DBS

   6 = Participant forgot to bring DBS remote to visit

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

   8 = Site scheduling issues during completion of visit

   9 = Other reason (please specify in comment box) *-> free-text comment box to appear*

6. Date of most recent PD medication dosing: **_____ / _____/ _____**

7. Time of most recent PD medication dosing prior to MDS-UPDRS part III being assessed (24-hour clock): **_____ : _____**

8. Time that DBS was turned off (24-hour clock): **_____ : _____ or N/A**

9. Time that the MDS-UPDRS part III "OFF" exam was administered prior to dosing in clinic: (24-hour clock): **_____ : _____**

For the ON MDS-UPDRS Part III:

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

    Yes **No**

11. If no, please select the reason:

    01 = Typical "ON" state was not reached
    02 = Scheduling issues
    03 = Other reason (specify in the comment section below)

12. Date of most recent PD medication dosing: **_____ / _____/ _____**

13. Time of most recent/in clinic PD medication dosing (24-hour clock): **_____ : _____**

14. Time that DBS was turned on (24-hour clock): **_____ : _____ or N/A**

15. Time that the MDS-UPDRS part III "ON" exam was administered after dosing in clinic:

    (24-hour clock): **_____ : _____**

Comments if applicable:

-

_____
_____
_____

PPMI
VISIT STATUS

1. Indicate the type of visit that was conducted:
    - Standard protocol visit
    - Diagnostic visit
    - Need for PD Therapy visit
    - Premature Withdrawal visit
    - Unscheduled visit

1a. Was this visit conducted as an Out of Clinic visit? No / Yes

If "yes" to Q1a, display question 1b:

1b) 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

If visit is out of the 45 day window of Target Visit date, complete q2

2. Indicate the primary reason the visit was not conducted within window:

1 = Scheduling issue with participant/caregiver
2 = Scheduling issue with site
3 = Family/Social issues
4 = Could not contact participant within window
5 = Transportation/Travel issues
6 = Medical problems
7 = Military duty
8 = Financial issues
9 = Hospitalized/Institutionalized
10 = Other, please specify:

PPMI

Vital Signs

1. Weight (in Kilograms) *Baseline and annual only* _____ *kg*
2. Height (in centimeters) *Baseline and annual only* _____ *cm*
3. Temperature - oral (Celsius) _____ C
4. Army used to measure blood pressure **RIGHT** **LEFT**
5. Supine blood pressure *taken after participant is supine 1-3 minutes*

   Systolic/diastolic (mmHg) _____ /_____
6. Supine heart rate *taken after participant is supine 1-3 minutes*

   (Beats per minute) _____
7. Standing blood pressure *taken after participant is standing 1-3 minutes*

   Systolic/diastolic (mmHg) _____ /_____
8. Standing heart rate *taken after participant is standing 1-3 minutes*

   (Beats per minute) _____

PPMI

PARTICIPANT MOTOR FUNCTION QUESTIONNAIRE

A. Who completed this questionnaire?

1 = participant 2 = caregiver 3 = Participant and Caregiver

When answering these questions, please think about your current abilities.

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

PPMI

UNIVERSITY OF PENNSYLVANIA SMELL IDENTIFICATION TEST – UPSIT

Only one answer choice should be selected for each question.

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

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.

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 DaTscan imaging.

   YES NO

3. Confirmation that participant is eligible based on Screening DaTscan 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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.

   YES NO

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

   YES NO

PPMI

Parkinson's Disease 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

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

   YES NO

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

   YES NO

4. 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

5. Hoehn and Yahr stage I or II at Baseline.

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.
   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

2. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit.

   YES NO

3. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

   YES NO

4. 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).

   YES NO

5. A clinical diagnosis of dementia as determined by the investigator.

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

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

    YES NO

PPMI

Parkinson's Disease-LRRK2 or GBA 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

2. A diagnosis of Parkinson disease for 2 years or less 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. Hoehn and Yahr stage I or II at Baseline.

   YES NO

5. Confirmation of causative LRRK2 or GBA (willingness to undergo genetic testing as part of genetic screening and be informed of genetic testing results, or documentation of prior genetic testing results).

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.
   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

PPMI

Parkinson's Disease-SNCA or rare genetic variant 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.

Inclusion Criteria:

1. Male or female age 30 years or older at Screening Visit.

   YES NO

2. Parkinson disease diagnosis 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. Hoehn and Yahr stage I, II, or III at Baseline.

   YES NO

5. Confirmation of causative SNCA or Parkin mutation (willingness to undergo genetic testing as part of genetic screening and be informed of genetic testing results, or approved documentation of prior genetic testing results).

   YES NO

6. 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 DaTscan imaging.

   YES NO

7. Confirmation that participant is eligible based on Screening DaTscan imaging.

   YES NO

8. Able to provide informed consent.

   YES NO

9. 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 Screening DaTscan imaging test prior to injection of DaTscan

   YES NO

Exclusion Criteria:

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

   YES NO

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

   YES NO

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

   YES NO

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

   YES NO

PPMI
PRODROMAL HISTORY
[STANDARD EDC HEADER INFO]

1. Indicate how the participant was identified for Prodromal Screening:
    a. Participant was referred by the IU Screening Core
    b. Participant was identified by the PPMI clinical site

2. Is the participant in the REM sleep behavior disorder (RBD) sub-group? Yes / No
If Q1 = a AND Q2 = Yes, complete Q2a.
If Q1 = b AND Q2 = Yes, complete Q2b and Q2c.

2a. Indicate the information supporting selection to RBD sub-group as confirmed by the IU Screening Core:
    a. Participant reported RBD Yes / No
    b. RBD questionnaires Yes / No

2b. Does the participant have a clinical diagnosis of RBD? Yes / No
If yes, complete questions below. If no, skip to Q2c.
i. Indicate date of RBD symptom onset: [calendar picker or enter date]
ii. Indicate date of clinical diagnosis: [calendar picker or enter date]

2c. Does the participant have a polysomnography (PSG) consistent with diagnosis of RBD? Yes / No
If yes, complete questions below. If no, skip to Q3.
i. Indicate date of RBD symptom onset: [calendar picker or enter date]
ii. Indicate date of PSG: [calendar picker or enter date]

3. Is the participant in the genetic variant subgroup? Yes / No
If Q1 = a or b, AND Q3 = Yes, complete Q3a.
3a. Indicate how test results were confirmed:
    1 = Genetic testing completed through the IU Screening Core
    2 = Previous genetic test report reviewed and approved by the IU Screening Core

*If Q2 = No **and** Q3 = No, complete Q4*

4. Is the participant in the hyposmia (general risk) subgroup? Yes / No
If Q1 = a AND Q4 = Yes, complete Q4a and Q4b.
If Q1 = b AND Q4 = Yes, complete Q4a, Q4b, Q4c.

4a. Does the participant have a biological first degree family member with PD Yes / No
4b. Does the participant have a known synuclein positive biopsy Yes / No
4c. Does the participant have previously known hyposmia (testing completed prior to PPMI participation) Yes / No

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.

Inclusion Criteria:

1. Confirmation that participant is eligible based on centrally determined predictive criteria including the University of Pennsylvania Smell Identification Test (UPSIT).
    a. For participants in PPMI Remote, referral to the clinical site confirms predictive eligibility.
    b. For participants identified by the clinical site, predictive criteria are based on generalized risk such as first degree biologic relative, known risk of PD including RBD, or known genetic variants associated with PD risk.
        i. Additionally, confirmation of UPSIT eligibility during the Screening visit prior to DaTscan.

    YES NO
2. Male or female age 60 years or older (except age 30 years or older for SNCA, or rare genetic mutations (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 DaTscan imaging.

    YES NO
4. Confirmation that participant is eligible based on Screening DaTscan imaging.

    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 Screening DaTscan imaging test prior to injection of DaTscan

    YES NO

Exclusion Criteria:

1. Clinical diagnosis of PD, other parkinsonism, or dementia.

YES NO

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

   YES NO

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

   YES NO

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.

   YES NO

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

   YES NO

PPMI Skin Biopsy

1. Was skin biopsy completed? (0 = No, 1 = Yes)

1a. If "no", please specify reason below:

1 = Participant declined biopsy

2 = Procedure attempted unsuccessfully, please specify: _____

3 = Other, specify: _____

2. Was lidocaine anesthesia administered? (0 = No, 1 = Yes, 2 = other anesthetic, please specify _____)

3. Was a formalin-fixed specimen collected? (Yes/No)
If Q3 = yes, Q3a-Q3e are required. If Q3 = no, do not display

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

3b. What type of wound closure was used?

1 = dressing only
2 = steri strips
3 = suture
4 = 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? (Yes/No)
If Q4 = yes, Q4a – Q4e are required. If Q4 = no, do not display

4a. On which side of the body was the cervical paravertebral biopsy performed?
1 = right
2 = left

4b. What type of wound closure was used?

1 = dressing only
2 = steri strips

3 = suture
4 = other (specify) _____

4c. Time that biopsy was collected: (24-hour clock)

4d. Time biopsy specimen was frozen: (24-hour clock)

4e. Frozen/Freezer Temperature (in Celsius): _____