**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.

<table>
<thead>
<tr>
<th>AE #</th>
<th>Adverse Event</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>Stop Date (mm/dd/yyyy)</th>
<th>Severity</th>
<th>Serious</th>
<th>Relationship to Study</th>
<th>How is it related</th>
<th>Resulted in withdrawal from study</th>
<th>Complete when resolved (or up to 30 days post-procedure)</th>
<th>Primary Outcome</th>
<th>How is it related</th>
<th>Complete when resolved (or up to 30 days post-procedure)</th>
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<tbody>
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<td>1=mild 2=moderate 3=severe</td>
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<td>1=unrelated 2=unlikely 3=possible 4=probably 5=definite</td>
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<td>1=DaTscan 2=LP 3=skin biopsy 4=AV-133 5=MK-6240 PET Scan</td>
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<td>1=recovered 2=under treatment/observation 3=change in AE characteristic 4=sequela 5=fatal 6=unknown</td>
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**CONFIDENTIAL**

05MAR21

**Not for distribution**
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.
1. Blood for clinical labs: (0 = Not collected, 1 = Collected)
   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

<table>
<thead>
<tr>
<th>Row</th>
<th>Medication Name (generic preferred)</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Indication (See options below)</th>
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</table>

### Indication Selections*:
- Anxiety
- Atrial Fibrillation/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*
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:

________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

Participant ID
Visit Number
Site #

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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”.

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

<table>
<thead>
<tr>
<th>Family Type</th>
<th>Number of Family Members</th>
<th>Number with PD or Parkinsonism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Mother</td>
<td>1</td>
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<tr>
<td>Biological Father</td>
<td>1</td>
<td></td>
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<tr>
<td>Full Brothers</td>
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<tr>
<td>Full Sisters</td>
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<tr>
<td>Maternal Half Siblings</td>
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<tr>
<td>Paternal Half Siblings</td>
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<tr>
<td>Maternal Grandmother</td>
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<td>Maternal Grandfather</td>
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<td>Maternal Aunts and Uncles</td>
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<td>Paternal Aunts and Uncles</td>
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<tr>
<td>Maternal Cousins</td>
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<tr>
<td>Paternal Cousins</td>
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<tr>
<td>Children</td>
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</tbody>
</table>

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%)

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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:

<table>
<thead>
<tr>
<th>Normal</th>
<th>Abnormal</th>
<th>Cannot Assess</th>
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If abnormal, describe briefly:
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2. Head/Neck/Lymphatic:

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<th>Normal</th>
<th>Abnormal</th>
<th>Cannot Assess</th>
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If abnormal, describe briefly:
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3. Eyes:

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<tr>
<th>Normal</th>
<th>Abnormal</th>
<th>Cannot Assess</th>
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If abnormal, describe briefly:
______________________________________________________________________
______________________________________________________________________

4. Ears/Nose/Throat:

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<th>Normal</th>
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<th>Cannot Assess</th>
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If abnormal, describe briefly:
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5. Lungs:

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<th>Normal</th>
<th>Abnormal</th>
<th>Cannot Assess</th>
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If abnormal, describe briefly:

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6. Cardiovascular (including peripheral vascular):

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<th>Normal</th>
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<th>Cannot Assess</th>
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If abnormal, describe briefly:

______________________________________________________________________
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7. Abdomen:

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<th>Cannot Assess</th>
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If abnormal, describe briefly:

______________________________________________________________________
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8. Musculoskeletal:

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If abnormal, describe briefly:

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

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<th>Normal</th>
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If abnormal, describe briefly:

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10. Psychiatric:

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<th>Abnormal</th>
<th>Cannot Assess</th>
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If abnormal, describe briefly:

______________________________________________________________________
______________________________________________________________________

11. Other:

Specify and describe briefly:

______________________________________________________________________
______________________________________________________________________
PPMI
GERIATRIC 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.
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.
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.
14. Do you feel that your situation is hopeless? 14.
15. Do you think that most people are better off than you are? 15.

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 methylldopa, 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
# Informed Consent Tracking Log

<table>
<thead>
<tr>
<th>Study Template Version Date</th>
<th>Site Version Date</th>
<th>Site IRB Approval Date</th>
<th>Date ICF Signed</th>
<th>Reason for Consent</th>
<th>Consent to share contact info with FOUND Y/N</th>
<th>Consent to share contact info with Pathology Core Y/N/NA</th>
<th>Consent to re-contact for use of information Y/N</th>
<th>Consent to re-contact for other research Y/N</th>
<th>Comment</th>
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<tr>
<td>Row</td>
<td>Medication Name (generic preferred)</td>
<td>Dose Strength</td>
<td>Units</td>
<td>Dose taken (1 tab, 2 tab etc)</td>
<td>Dose frequency per day (numeric only- do not use TID, etc)</td>
<td>Start Date</td>
<td>Stop Date</td>
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</tbody>
</table>
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/YYYY 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 dry ice: (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 = Hematol/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)

<table>
<thead>
<tr>
<th>Row #</th>
<th>Category (See KEY above)</th>
<th>Date of Diagnosis (MM/DD/YY)</th>
<th>Enter diagnosed medical conditions. Specify the disorder/diagnosis and use only one line per description. DO NOT ABBREVIATE.</th>
<th>Resolved</th>
<th>Date of Resolution (MM/DD/YYYY)</th>
</tr>
</thead>
<tbody>
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</table>
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:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Participant ID
Visit Number

CONFIDENTIAL 05MAR21 Not for distribution
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
Cognition Function – Short Form

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

<table>
<thead>
<tr>
<th>How much DIFFICULTY do you currently have…</th>
<th>None</th>
<th>A little</th>
<th>Somewhat</th>
<th>A lot</th>
<th>Cannot do</th>
</tr>
</thead>
<tbody>
<tr>
<td>reading and following complex instructions (e.g., directions for a new medication)?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>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)?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>managing your time to do most of your daily activities?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>learning new tasks or instructions?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

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# PPMI

## NEURO-QoL 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...

<table>
<thead>
<tr>
<th>Question</th>
<th>None</th>
<th>A little</th>
<th>Somewhat</th>
<th>A lot</th>
<th>Cannot do</th>
</tr>
</thead>
<tbody>
<tr>
<td>writing notes to yourself, such as appointments or 'to do' lists?</td>
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<td>understanding family and friends on the phone?</td>
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<tr>
<td>carrying on a conversation with a small group of familiar people (e.g., family or a few friends)?</td>
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<tr>
<td>organizing what you want to say?</td>
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<tr>
<td>speaking clearly enough to use the telephone?</td>
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</table>

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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.

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Level of Difficulty</th>
<th>Without Any Difficulty</th>
<th>With a Little Difficulty</th>
<th>With Some Difficulty</th>
<th>With Much Difficulty</th>
<th>Unable to Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>N090092</td>
<td>Are you able to get on and off the toilet?...</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>N090092</td>
<td>Are you able to step up and down curbs?...</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>N090092</td>
<td>Are you able to get in and out of a car?.....</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>N090092</td>
<td>Are you able to get out of bed into a chair?........................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>N090092</td>
<td>Are you able to push open a heavy door?..</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>N090092</td>
<td>Are you able to run errands and shop?.......</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>N090092</td>
<td>Are you able to get up off the floor from lying on your back without help?...........</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>N090092</td>
<td>Are you able to go for a walk of at least 15 minutes?.....................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

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English
March 6, 2014

Page 1 of 1
Upper Extremity Function (Fine Motor, ADL) – Short Form

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Without any difficulty</th>
<th>With a little difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Unable to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you able to turn a key in a lock?...........</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Are you able to brush your teeth?...............</td>
<td>□</td>
<td>□</td>
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<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Are you able to make a phone call using a touch tone key-pad?.........................</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Are you able to pick up coins from a table top?........................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
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<td>□</td>
</tr>
<tr>
<td>Are you able to write with a pen or pencil?.................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Are you able to open and close a zipper?...</td>
<td>□</td>
<td>□</td>
<td>□</td>
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<td>□</td>
</tr>
<tr>
<td>Are you able to wash and dry your body?..</td>
<td>□</td>
<td>□</td>
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</tr>
<tr>
<td>Are you able to shampoo your hair?...........</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

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Page 1 of 1

English
March 6, 2014
### 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 methylidopa, 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 methylldopa, 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 methylldopa, 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.
   \textit{(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:

<table>
<thead>
<tr>
<th>Participant</th>
<th>Caregiver/Informant</th>
<th>Participant and Caregiver/Informant</th>
</tr>
</thead>
</table>

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
10.d RLS
10.e Narcolepsy
10.f Depression
10.g Epilepsy
10.h Inflammatory disease of the brain
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/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?
   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)
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: _______________________________________

CONFIDENTIAL
05MAR21
Not for distribution
## PPMI

### SURGERY FOR PD LOG

<table>
<thead>
<tr>
<th>Date of Surgery</th>
<th>Type of Surgery</th>
<th>Side</th>
<th>Location (Choose all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### “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
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 methylldopa, 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 methylldopa, 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
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 $Q_1 = a$ AND $Q_2 = Yes$, complete $Q_2a$.
   If $Q_1 = b$ AND $Q_2 = Yes$, complete $Q_2b$ and $Q_2c$.

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 $Q_2c$.
   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 $Q_3$.
   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 $Q_1 = a$ or $b$, AND $Q_3 = Yes$, complete $Q_3a$.
   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 $Q_2 = No$ and $Q_3 = No$, complete $Q_4$

4. Is the participant in the hyposmia (general risk) subgroup? Yes / No
   If $Q_1 = a$ AND $Q_4 = Yes$, complete $Q_4a$ and $Q_4b$.
   If $Q_1 = b$ AND $Q_4 = Yes$, complete $Q_4a$, $Q_4b$, $Q_4c$.

   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
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 methyl dopa, 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
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
<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Visit Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

Visit Number

- 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): ________