PPMI

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PROTOCOL DEVIATION CODE