PPMI
INCLUSION/EXCLUSION - PRODROMAL (Amend 8)

1 3 2 | 1 0

SUBJECT ID | VISIT NO

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

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

6. Confirmation from imaging core that screening dopamine transporter SPECT scan (or V-MAT-2 PET scan for sites where DaTSCAN is not available) is read as eligible. 6. ☐

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

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

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

12. Male or female age 60 years or older. 12. ☐

13. Subject has at least one of the following characteristics: 13. ☐

a.) Confirmation from olfactory core that olfaction as determined by UPSIT is at or below the 10th percentile by age and gender

b.) Confirmation from sleep core that subject's Polysomnography meets criteria for RBD and/or clinical diagnosis of RBD by site investigator including existing PSG

To be **ELIGIBLE** for study participation **ALL** answers to items 6 - 8 and 12 - 13 must be **1 = Yes,** and item 9 must be **1 = Yes** if female of child bearing potential

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

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. ☐
16.	Current or active clinically significant neurological disorder or psychiatric disorder (in the opinion of the Investigator).	16. ☐
17.	GDS score greater than or equal to 10, or GDS score of 5 - 9 without Investigator discretion to enter study.	17. ☐
18.	STAI Form Y-1 greater than or equal to 54 without Investigator discretion to enter study.	18. ☐
19.	A clinical diagnosis of Parkinson disease at the Screening visit as determined by the Investigator.	19. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 5 -11 and 16 - 19 must be **0 = No**