

**PPMI**

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**INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)**

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SUBJECT ID 

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VISIT NO 

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INITIALS 

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SITE NO 

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VISIT DATE 

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

- 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.
  
- 10. Male or female age 30 years or older at Screening. 10.

To be **ELIGIBLE** for study participation **ALL** answers to items 7, 8 and 10 must be **1 = Yes**, and item 9 must be **1 = Yes** if female of child bearing potential

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

- 6. Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyl dopa, 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.

PPMI

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INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)

1 1

SUBJECT ID

VISIT NO

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

- 11. Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator). 11.
  
- 13. Current or active clinically significant neurological disorder (in the opinion of the Investigator). 13.
  
- 14. First degree relative with idiopathic PD (parent, sibling, child). 14.
  
- 15. MoCA score less than or equal to 26. 15.

To be **ELIGIBLE** for study participation **ALL** answers to items 6-15 must be **0 = No**

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

PROTOCOL DEVIATION CODE