

PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research

PPMI Study CRF and Assessments

For Amendment-5
TAP-PD
AV-133
Version 4.0

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	Smell Test Self Reporting Questionnaire (SRQ) Italian
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PPMI Schedule of Activities
PARKINSON DISEASE (PD) SUBJECTS

Visit Description	Visit Number	Level #	SC -1	BL 0	T02 3	V01 6	T03 9	V03 12	T04 15	T05 18	V05 21	T06 24	T07 27	T08 30	V07 33	T09 36	V08 39	T10 42	T11 45	V09 48	T12 51	V10 54	T13 57	V14 57	T15 60	V16 FNL	PW	ST	U0X							
Confidential Subject Identification Log		I/C																																		
Written Informed Consent		I/C/S																																		
Screening/Demographics		02	I/C																																	
Socio-Economics		04	I/C																																	
CTCC Unique ID		06	I/C/S																																	
Inclusion/Exclusion - PD Amend 4		10	I/C	I/C																																
Telephone Follow-up		12	I/C	I/C	I/C	I/C	I/C		I/C	I/C	I/C		I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C									
PD Features		14	I/C																																	
Primary Diagnosis		16	I																									I	I	I						
Diagnostic Features		17																									I	I	I	I						
Medical History (General)		18	I/C																																	
Family History (PD)		20	I/C																																	
General Neurological Exam		22	I																									I	I	I ^k	I ^g					
General Physical Exam		24	I/C																																	
Vital Signs		26	I/C	I/C ^c	I/C	I/C	I/C	I/C	I/C ^c	I/C	I/C ^c	I/C	I/C	I/C	I/C	I/C ^c	I/C	I/C	I/C ^c	I/C	I/C	I/C ^c	I/C	I/C ^c	I/C	I/C	I/C	I/C ^c	I/C	I/C	I/C					
Pregnancy Form		28	I/C																										I/C	I/C	I/C	I/C				
Use of PD Medication		30																																		
MDS-UPDRS/Hoehn & Yahr ^b		I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/C	I/C	I/C	I/C	I/C	I/C	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S					
Modified S&E Activities of Daily Living		32	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I			
MDS-UPDRS/Hoehn & Yahr (Post Dose) ^j		34																																		
Physical Activity Scale (PASE)																																				
Hopkins Verbal Learning Test – Revised		36	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Benton Judgment of Line Orientation			C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Semantic Fluency		38	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Letter Number Sequencing (PD)		40	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Symbol Digit Modalities Test		42	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Montreal Cognitive Assessment (MoCA)		43	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
Epworth Sleepiness Scale		44	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
REM Sleep Disorder Questionnaire		46	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
Geriatric Depression Scale (GDS-15)		48	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
State-Trait Anxiety Inventory for Adults																																				
QUIP		50	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
SCOPA-AUT		52	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
Cognitive Categorization		53	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I ^k	I ^g				
Olfactory Testing (UPSIT)		54	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S	C/S						
DNA Sample [®]		56	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C						
Laboratory Procedures		58		I/C ^f	I/C	I/C	I/C ^f	I/C	I/C	I/C ^f	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C						
Clinical Labs		59	I/C																																	
Whole Blood Sample		78		I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C						
Magnetic Resonance Imaging (Structural)		60		I																																
Magnetic Resonance Imaging (DTI) ^e		60		I																																
DaTSCAN Imaging ^m		62	I																																	
VMAT-2 Imaging ^m (see AV-133 SoA)			I																																	
Lumbar Puncture		64		I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I			
Signature Form		66	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I			
Adverse Event Log ^a		68	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C					
Current Medical Conditions Log		70		I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C					
Concomitant Medication Log		72	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C	I/C					
Conclusion of Study Participation		74																																		
Subject Site Transfer Form		76																																		

^a Adverse events assessed at the visit and by phone 7 to 10 days following LP and/or DaTSCAN injection.

* if not done in last 3 mths; ^ if not done in last 12 mths; [@] may be done at BL if not at SC

^c Height and weight also collected

ST = Symptomatic Therapy

^e Diffusion tensor MRI scan and resting state sequences conducted at selected sites.

PW = Premature Withdrawal

^f Biomeric urine sample also collected.

FNL = Final

^g Conduct as clinically indicated - see protocol Sect. 5.3.17.

I = Assessment must be completed by Investigator (or as delegated)

^h Part IV once subject has started PD medication.

I/C = Assessment completed by Investigator and/or Coordinator

ⁱ Repeat assessment 1 hr post treatment for subjects on levodopa or dopamine agonist.

I/S = Assessment completed by Investigator and Subject (or as delegated)

^j Not conducted depending on when ST visit conducted - see protocol Sect. 5.3.19.

C/S = Assessment completed by Coordinator and Subject (or as delegated)

^m DAT completed at all sites except Australia; VMAT completed in Australia and selected U.S. sites.

S = Assessment completed by Subject

PPMI Schedule of Activities
HEALTHY CONTROL (HC) SUBJECTS - Amend 5

Visit Description	Visit Number	Level #	SC	T01	BL	T02	V01	V02	T03	V03	V04	T04	T05	V05	T06	V06	T07	T08	V07	T09	V08	T10	T11	V09	T12	V10	T13	T14	V11	T15	V12	T16	FNL	PW	UOX					
Confidential Subject Identification Log		-1	I/C		0		3	6		9	12		15	18	21	24		27	30	33	36		39	42	45	48		51	54	57	60									
Written Informed Consent			S																																					
Screening/Demographics		02	I/C																																					
Socio-Economics		04	I/C																																					
CTCC Unique ID		06	I/C/S																																					
Inclusion/Exclusion - HC Amend 4		11	I/C		I/C																																			
Telephone Follow-up		12		I/C		I/C				I/C			I/C	I/C		I/C		I/C	I/C		I/C		I/C	I/C		I/C		I/C		I/C										
Primary Diagnosis		16	I								I					I			I				I				I			I		I								
Diagnostic Features		17									I ^s					I ^s			I ^s				I ^s				I ^s			I ^s										
Medical History (General)		18	I/C																																					
Family History (PD)		20	I/C																																					
General Neurological Exam		22	I								I					I			I				I				I			I		I	I ^g							
General Physical Exam		24	I/C																																					
Vital Signs		26	I/C		I/C ^c		I/C	I/C		I/C	I/C ^c		I/C		I/C ^c		I/C		I/C ^c		I/C		I/C ^c		I/C		I/C ^c		I/C ^c	I/C										
Pregnancy Form		28	I/C																																					
MDS-UPDRS/Hoehn & Yahr											I/S					I/S							I/S				I/S			I/S		I/S	I/S							
Physical Activity Scale (PASE)												C/S				C/S			C/S				C/S			C/S		C/S	C/S		C/S	C/S								
Hopkins Verbal Learning Test – Revised		36			C/S						C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Benton Judgment of Line Orientation					C/S						C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Semantic Fluency		38		C/S							C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Letter Number Sequencing (PD)		40		C/S							C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Symbol Digit Modalities Test		42		C/S							C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Montreal Cognitive Assessment (MoCA)		43	C/S								C/S				C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S		C/S	C/S								
Epworth Sleepiness Scale		44		S							S				S		S		S		S		S		S		S		S	S		S								
REM Sleep Disorder Questionnaire		46		S							S				S		S		S		S		S		S		S		S	S		S	S							
Geriatric Depression Scale (GDS-15)		48		S							S				S		S		S		S		S		S		S		S	S		S	S							
State-Trait Anxiety Inventory for Adults				S							S				S		S		S		S		S		S		S		S		S	S								
QUIP		50		S							S				S		S		S		S		S		S		S		S	S		S	S							
SCOPA-AUT		52		S							S				S		S		S		S		S		S		S		S	S		S	S							
Cognitive Categorization		53		I							I				I		I		I		I		I		I		I		I	I		I	I							
Olfactory Testing (UPSIT)		54		C/S																																				
DNA Sample [®]		56	I/C																																					
Laboratory Procedures		58		I/C ^t		I/C	I/C ^t			I/C	I/C ^t		I/C		I/C ^t		I/C	I/C ^t		I/C		I/C ^t		I/C	I/C ^t		*I/C ^t													
Clinical Labs		59	I/C									I/C				I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C	I/C ^g									
Whole Blood Sample		78		I/C		I/C	I/C			I/C	I/C		I/C		I/C		I/C	I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C								
Magnetic Resonance Imaging (Structural)		60		I																																				
Magnetic Resonance Imaging (DTI) ^a		60		I							I				I																									
DaTSCAN Imaging ^m		62	I																																					
VMAT-2 Imaging ^m (see AV-133 SoA)			I																																					
Lumbar Puncture		64		I		I	I	I		I				I		I		I		I		I		I		I		I		I		I		I		*I				
Signature Form		66	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I					
Adverse Event Log ^a		68	I/C		I/C		I/C			I/C			I/C			I/C			I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C					
Current Medical Conditions Log		70		I/C		I/C	I/C			I/C	I/C		I/C		I/C		I/C	I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C	I/C					
Concomitant Medication Log		72	I/C	I/C	I/C	I/C	I/C			I/C	I/C		I/C		I/C		I/C	I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C	I/C					
Conclusion of Study Participation		74																																						
Subject Site Transfer Form		76																																						

I/C if needed

^a Adverse events assessed at the visit and by phone 7 to 10 days following LP and/or DaTSCAN injection.

^c Height and weight also collected.

^d Diffusion tensor MRI scan and resting state sequences conducted at selected sites.

^f Biomimic urine sample also collected.

^g Conduct as clinically indicated - see protocol Sect. 5.3.17

^m DAT completed at all sites except Australia; VMAT completed in Australia and selected U.S. sites.

* if not done in last 3 mths; ^ only if withdrawal within first 12 mths and MRI DTI not done in last 6 mths

^s only if change in primary diagnosis; [®] may be done at BL if not at SC

PW = Premature Withdrawal

FNL = Final

I = Assessment must be completed by Investigator (or as delegated)

I/C = Assessment completed by Investigator and/or Coordinator

I/S = Assessment completed by Investigator and Subject (or as delegated)

I/C/S = Assessment completed by Coordinator and Subject (or as delegated)

S = Assessment completed by Subject

**PPMI Schedule of Activities
SWEDD SUBJECTS**

Visit Number		Level	ReSC	T01	BL	T02	V01	V02	T03	V03	V04	T04	T05	V05	T06	V06	T07	FNL	PW	ST	U0X		
Visit Description	Months (+30 days)		#	-1	0	3	6		9	12		15	18	21	24								
Written Informed Consent			I/C/S																				
Screening/Demographics	02		I/C																				
Inclusion/Exclusion - SWEDD Amend 4	86		I/C	I/C																			
Telephone Follow-up	12		I/C		I/C				I/C			I/C	I/C		I/C	I/C							
Medical History (General)	18		I/C																				
Family History (PD)	20		I/C								I					I		I	I ^k	X ^g			
General Neurological Exam	22		I																				
General Physical Exam	24		I/C																				
Vital Signs	26		I/C	I/C ^c		I/C	I/C		I/C	I/C ^c			I/C		I/C ^c		I/C ^c	I/C	I/C				
Pregnancy Form	28				I/C											I/C			I/C				
Use of PD Medication	30					I/C	I/C		I/C	I/C			I/C		I/C	I/S		I/C	I/C				
MDS-UPDRS/Hoehn & Yahr ^h			I/S	I/S	I/S	I/S			I/S	I/S									I/S	I/S			
Modified Schwab and England Activities of Daily Living	32		I	I	I	I			I	I			I	I				I	I				
MDS-UPDRS/Hoehn & Yahr (Post Dose) ^j	34									I					I				I				
Physical Activity Scale (PASE)										C/S						C/S		C/S					
Clinical Diagnosis and Management Questionnaire	88			I		I	I		I	I			I		I		I [#]	I [#]					
Hopkins Verbal Learning Test – Revised	36		C/S							C/S					C/S		C/S	C/S ^k					
Benton Judgment of Line Orientation			C/S							C/S					C/S		C/S	C/S ^k					
Semantic Fluency	38		C/S							C/S					C/S		C/S	C/S ^k					
Letter Number Sequencing (PD)	40		C/S							C/S					C/S		C/S	C/S	C/S ^k				
Symbol Digit Modalities Test	42		C/S							C/S					C/S		C/S	C/S	C/S ^k				
Montreal Cognitive Assessment (MoCA)	43	C/S								C/S					C/S		C/S	C/S	C/S ^k				
Epworth Sleepiness Scale	44		S			S			S					S		S	S	S	S				
REM Sleep Disorder Questionnaire	46		S			S			S					S		S	S	S	S				
Geriatric Depression Scale (GDS-15)	48		S			S			S					S		S	S	S	S				
State-Trait Anxiety Inventory for Adults			S		S	S			S					S		S	S	S	S				
QUIP	50		S			S			S					S		S	S	S	S				
SCOPA-AUT	52		S		S	S			S					S		S	S	S	S				
Cognitive Categorization	53		I			I			I					I		I	I ^k						
Olfactory Testing (UPSiT)	54		C/S																				
Laboratory Procedures	58		I/C ^f		I/C	I/C ^f			I/C	I/C ^f			I/C		I/C ^f		*I/C ^f	I/C ^f					
Clinical Labs	59	I/C										I/C			I/C		I/C	I/C ^k	I/C ^g				
Whole Blood Sample	78		I/C		I/C	I/C			I/C	I/C			I/C			I/C		I/C	I/C				
Magnetic Resonance Imaging (Structural)	60		I													I		^I					
Magnetic Resonance Imaging (DTI) ^e	60		I																				
DaTSCAN Imaging ^m	62														I		^I	I ^k					
VMAT-2 Imaging ^m (see AV-133 SoA)														I		^I	I ^k						
Lumbar Puncture	64		I			I			I					I				*I	I ^k				
Signature Form	66	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Adverse Event Log ^a	68		I/C			I/C			I/C			I/C			I/C		I/C	I/C	I/C				
Current Medical Conditions Log	70	I/C		I/C		I/C	I/C		I/C	I/C				I/C		I/C	I/C	I/C	I/C	I/C			
Concomitant Medication Log	72	I/C		I/C		I/C	I/C		I/C	I/C				I/C		I/C	I/C	I/C	I/C	I/C			
Conclusion of Study Participation	74																I/C						
Subject Site Transfer Form	76																						

^a Adverse events assessed at the visit and by phone 7 to 10 days following LP and/or DaTSCAN injection.

* if not done in last 3 mths; ^ if not done in last 12 mths

^b Height and weight also collected.

ReSC = Re-Screen

^c Diffusion tensor MRI scan and resting state sequences conducted at selected sites.

ST = Symptomatic Therapy

^d Biomeric urine sample also collected.

PW = Premature Withdrawal

^e Conduct as clinically indicated - see protocol Sect. 5.3.17

FNL = Final

^f Part IV once subject has started PD medication.

I = Assessment must be completed by Investigator (or as delegated)

^g Repeat assessment 1 hr post treatment for subjects on levodopa or dopamine agonist.

I/C = Assessment completed by Investigator and/or Coordinator

^h Not conducted depending on when ST visit conducted - see protocol Sect. 5.3.19.

I/S = Assessment completed by Investigator and Subject (or as delegated)

ⁱ DAT completed at all sites except Australia; VMAT completed in Australia and selected U.S. sites.

C/S = Assessment completed by Coordinator and Subject (or as delegated)

^j Contact PPMI Information Analyst to add page to event.

S = Assessment completed by Subject

12/20/2012

PPMI Schedule of Activities
PRODROMAL SUBJECTS - Amend 5

Visit Number	Level #	SC	T01	BL	T02	V01	V02	T03	V03	V04	T04	T05	V05	T06	V06	T07	T08	V07	T09	V08	T10	T11	V09	T12	V10	T13	FNL	PW	ST	UOX	
Visit Description	Months (+30 days)																														
Confidential Subject Identification Log		I/C		0		3	6		9	12		15	18	21	24		27	30	33	36		39	42	45	48						
Written Informed Consent		I/C/S																													
Screening/Demographics	02	I/C																													
Socio-Economics	04	I/C																													
CTCC Unique ID	06	I/C/S																													
Inclusion/Exclusion - Prodromal AM5	10	I/C	I/C																												
Telephone Follow-up	12	I/C	I/C																												
Prodromal Diagnostic Questionnaire	15	I		I	I	I	I		I	I		I		I		I/C	I/C		I/C	I/C		I/C	I/C		I/C	I/C	I/C	I/C			
Diagnostic Features	17		I	I	I	I	I		I	I		I		I		I	I	I	I	I	I	I	I	I	I	I	I	I			
Medical History (General)	18	I/C																													
Family History (PD)	20	I/C																													
General Neurological Exam	22	I																										I	I ^k	I ^g	
General Physical Exam	24	I/C																													
Vital Signs	26	I/C	I/C ^c		I/C	I/C		I/C	I/C ^c			I/C		I/C		I/C	I/C ^c		I/C	I/C ^c		I/C	I/C ^c			I/C ^c	I/C	I/C			
Pregnancy Form	28	I/C																										I/C	I/C		
Use of PD Medication	30																											I/C	I/C		
MDS-UPDRS/Hoehn & Yahr ^a		I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S	I/S			
Modified S&E Activities of Daily Living	32	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
MDS-UPDRS/Hoehn & Yahr (Post Dose) ^j	34																														
Physical Activity Scale (PASE)			C/S																											C/S	C/S
Hopkins Verbal Learning Test – Revised	36		C/S																											C/S	C/S ^k
Benton Judgment of Line Orientation			C/S																											C/S	C/S ^k
Semantic Fluency	38		C/S																											C/S	C/S ^k
Letter Number Sequencing (PD)	40		C/S																											C/S	C/S ^k
Symbol Digit Modalities Test	42		C/S																											C/S	C/S ^k
Montreal Cognitive Assessment (MoCA)	43	C/S																												C/S	C/S ^k
Epworth Sleepiness Scale	44		S		S		S		S			S		S		S		S		S		S		S		S		S	S		
REM Sleep Disorder Questionnaire	46		S		S		S		S			S		S		S		S		S		S		S		S		S	S		
Geriatric Depression Scale (GDS-15)	48	S					S		S			S		S		S		S		S		S		S		S		S	S		
State-Trait Anxiety Inventory for Adults		S					S		S			S		S		S		S		S		S		S		S		S	S		
QUIP	50		S		S		S		S			S		S		S		S		S		S		S		S		S	S		
SCOPA-AUT	52		S		S		S		S			S		S		S		S		S		S		S		S		S	S		
Cognitive Categorization	53		I		I		I		I			I		I		I		I		I		I		I		I		I ^k			
Olfactory Testing (UPSIT)	54		C/S																												
DNA Sample [@]	56		I/C																												
Laboratory Procedures	58		I/C ^f		I/C	I/C ^f		I/C	I/C ^f			I/C		I/C ^f		I/C	I/C ^f		I/C	I/C ^f		I/C	I/C ^f		*I/C ^f	I/C ^f					
Clinical Labs	59	I/C																											I/C	I/C ^k	I/C ^g
Whole Blood Sample	78		I/C		I/C	I/C		I/C	I/C			I/C		I/C		I/C	I/C														
Magnetic Resonance Imaging (Structural)	60		I																												
Magnetic Resonance Imaging (DTI) ^e	60		I																												A ⁱ
DaTSCAN Imaging ^m	62	I																													A ⁱ
Lumbar Puncture	64		I		I		I		I			I		I		I		I		I		I		I		I		I ^k			
Signature Form	66	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I			
Adverse Event Log ^a	68	I/C	I/C		I/C		I/C		I/C			I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C			
Current Medical Conditions Log	70		I/C		I/C	I/C		I/C	I/C			I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C	I/C		
Concomitant Medication Log	72	I/C	I/C		I/C	I/C		I/C	I/C			I/C		I/C		I/C		I/C		I/C		I/C		I/C		I/C	I/C	I/C			
Conclusion of Study Participation	74																													I/C	
Subject Site Transfer Form	76																														

I/C If needed

^a Adverse events assessed at the visit and by phone 7 to 10 days following LP and/or DaTSCAN injection.

^b Height and weight also collected

^c Diffusion tensor MRI scan and resting state sequences conducted at selected sites.

^d Biomic urine sample also collected.

^e Conduct as clinically indicated - see protocol Sect. 5.3.17.

^f Part IV once subject has started PD medication.

^g Repeat assessment 1 hr post treatment for subjects on levodopa or dopamine agonist.

^h Not conducted depending on when ST visit conducted - see protocol Sect. 5.3.19.

^m DAT completed at all sites except Australia; VMAT completed in Australia and selected U.S. sites.

* if not done in last 3 mths; ^ if not done in last 12 mths; [@] may be done at BL if not at SC

ST = Symptomatic Therapy

PW = Premature Withdrawal

FNL = Final

I/C = Assessment must be completed by Investigator (or as delegated)

I/C = Assessment completed by Investigator and/or Coordinator

I/S = Assessment completed by Investigator and Subject (or as delegated)

C/S = Assessment completed by Coordinator and Subject (or as delegated)

S = Assessment completed by Subject

12/20/2012

**PPMI (¹⁸F-AV-133) Schedule of Activities
PARKINSON DISEASE (PD) SUBJECTS**

Visit Number		SC	V04	V06	V10	PW [^]	ST ^k
Months (+-30 days)		-45 days	Month 12	Month 24	Month 48	--	--
Assessments	Level #						
AV-133 Eligibility	11	I/C					
Clinical Labs ¹	59	I/C					
ECG	N/A	I/C					
Serum Pregnancy Test ²	63	I/C					
Urine Pregnancy Test ³	63	I/C	I/C	I/C	I/C	I/C	I/C
Vital Signs (Pre and Post Dose)	63	I/C	I/C	I/C	I/C	I/C	I/C
Weight	N/A	I/C	I/C	I/C	I/C	I/C	I/C
Physician Visit (Pre-Dose)	N/A	I	I	I	I	I	I
AV-133 Imaging	63	I	I	I	I	I	I
Physician Visit (End of Scan) ⁴	N/A	I	I	I	I	I	I
Adverse Event Assessment ⁵	68	I/C	I/C	I/C	I/C	I/C	I/C

I = Assessment completed by Investigator or as delegated.

I/C = Assessment completed by Investigator and/or Coordinator.

¹Clinical labs must be completed if screening labs are not available or were completed more than 60 days prior to the first injection of ¹⁸F-AV-133.

²The screening serum pregnancy test must be confirmed as negative in order for the subject to proceed with the first ¹⁸F-AV-133 injection.

³Performed on imaging day and must be confirmed as negative prior to injection for all females of childbearing potential.

⁴Or a physician's designee.

⁵During imaging day and 48 (+-24) hours following PET imaging.

[^]Imaging is conducted at PW only if imaging has not been done in last 12 months.

^kImaging is conducted at ST when ST visit replaces Month 12, Month 24, or Month 48 visit.

PW = Premature Withdrawal

ST = Symptomatic Therapy

4/23/2012

**PPMI (¹⁸F-AV-133) Schedule of Activities
HEALTHY CONTROL (HC) SUBJECTS**

Visit Number	SC	
Assessments	Level #	-45 days
AV-133 Eligibility	11	I/C
Clinical Labs ¹	59	I/C
ECG	N/A	I/C
Serum Pregnancy Test ²	63	I/C
Urine Pregnancy Test ³	63	I/C
Vital Signs (Pre and Post Dose)	63	I/C
Weight	N/A	I/C
Physician Visit (Pre-Dose)	N/A	I
AV-133 Imaging	63	I
Physician Visit (End of Scan) ⁴	N/A	I
Adverse Event Assessment ⁵	68	I/C

I = Assessment completed by Investigator or as delegated.

I/C = Assessment completed by Investigator and/or Coordinator.

¹ Clinical labs must be completed if screening labs are not available or were completed more than 60 days prior to the first injection of ¹⁸F-AV-133.

² The screening serum pregnancy test must be confirmed as negative in order for the subject to proceed with the first ¹⁸F-AV-133 injection.

³ Performed on imaging day and must be confirmed as negative prior to injection for all females of childbearing potential.

⁴ Or a physician's designee.

⁵ During imaging day and 48 (+-24) hours following PET imaging.

4/23/12

**PPMI (¹⁸F-AV-133) Schedule of Activities
SWEDD SUBJECTS**

Visit Number		V06	PW [^]	ST ^k
Months (+-30 days)		Month 24	--	--
Assessments	Level #			
Urine Pregnancy Test ³	63	I/C	I/C	I/C
Vital Signs (Pre and Post Dose)	63	I/C	I/C	I/C
Weight	N/A	I/C	I/C	I/C
Physician Visit (Pre-Dose)	N/A	I	I	I
AV-133 Imaging	63	I	I	I
Physician Visit (End of Scan) ⁴	N/A	I	I	I
Adverse Event Assessment ⁵	68	I/C	I/C	I/C

I = Assessment completed by Investigator

I/C = Assessment completed by Investigator and/or Coordinator

³ Performed on imaging day and must be confirmed as negative prior to injection for all females of childbearing potential.

⁴ Or a physician's designee

⁵ During imaging day and 48 (+-24) hours following PET imaging.

[^] Imaging is conducted at PW only if imaging has not been done in last 12 months.

^k Imaging is conducted at ST when ST visit replaces Month 12, Month 24, or Month 48 visit.

ST = Symptomatic Therapy

PW = Premature Withdrawal

PPMI

1 3 2

SCREENING/DEMOGRAPHICS

0 2

SUBJECT ID

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SITE NO

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Complete one form for each subject who has signed consent and is potentially eligible to participate in the study.

A. Check box if subject has signed consent

B. Date informed consent was signed:

B.

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DD

YYYY

C. Indicate the category for this subject:

(1 = Parkinson disease, 2 = Healthy Control, 3 = SWEDD, 4 = Prodromal)

C.

C1. If Question C = 4, indicate the primary group type:
(1 = Hyposmia, 2 = RBD, 3 = LRRK2)

C1.

1. Date of birth:

1.

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2. Gender (0 = Female of child bearing potential, 1 = Female of non-child bearing potential, 2 = Male)

2.

Women who are surgically sterile (hysterectomy or tubal ligation) or post-menopausal (last menstruation was 1 year or more prior to Screening Visit) are considered to be of non-child-bearing potential.

ETHNICITY

3. Do you identify your ethnicity as being Hispanic or Latino (Spanish origin)?
(0 = No, 1 = Yes, 2 = Unknown or not reported)

3. **RACE**

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

4.1

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

4.2

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

4.3

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

4.4

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

4.5

4.6 Do you identify yourself with a race category not specified on this form?
(0 = No, 1 = Yes, 2 = Unknown or not reported)

4.6

If Yes, please specify: _____

PPMI

1 3 2

SCREENING/DEMOGRAPHICS

0 2

SUBJECT ID

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SITE NO

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5. Projected Enrollment Date:

5.

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 YYYY

6. Referral Source:

01 = Site personnel
02 = PCP30 = Advocacy Organization
31 = Support Group6.

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80 = 1-800 Call center

04 = Family or Friend
10 = Newspaper/
Magazine Article
11 = Newspaper/
Magazine Ad58 = Clinicaltrials.gov
59 = PDtrials.org

60 = Specialist

14 = Radio/TV Ad
15 = Radio/TV Story
16 = Online News/
Blog/Other
17 = Out of Home Ad
18 = Event50 = Study Website
53 = Site Website
54 = Study Web Ad

99 = Other (specify in comments)

71 = MJFF Communication
72 = Another PD Subject
73 = Fox Trial Finder

6a. If referred by a medical professional (02, 60), provide name:

 7a. Declined

7b. Reason for declining:

01 = Confidentiality issues

03 = Protocol too restrictive
04 = Protocol too time intensive
05 = Travel requirements
06 = Family advised declining7b.

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07 = Physician advised declining
08 = Enrolled in other study
09 = Not interested (specify in comments)11 = Risks of Protocol
12 = Did not agree to lumbar puncture
99 = Other (specify in comments) 8a. Excluded

8b. Reason for exclusion:

01 = Exclusionary medication
02 = Other medical, psychiatric, or surgical condition
03 = Disease too advanced
04 = Dx uncertain

08 = Enrolled in other study

8b.

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06 = Did not meet other inclusion criteria (specify in comments) 12 = Abnormal Safety Labs
13 = SPECT Scan
99 = Other (specify in comments)

Comments:

PPMI**SOCIO-ECONOMICS**

1 3 2

0 4

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYY

1. Subject Education (number of years)

1.

4. Handedness (1 = Right, 2 = Left, 3 = Mixed)

4.

PPMI

1 3 2

CTCC UNIQUE ID

0 6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

MM

DD

YYYY

-
1. CTCC 9 digit Unique ID:

1. - -

If you have previously generated a Unique ID for this subject and have it on file, please enter it from your records.

If you have not yet generated a Unique ID for this subject, please go to the following website to do so: <https://www.ctcc.rochester.edu/uniqueid>

If you have previously generated a Unique ID for this subject, and do not have it on file, you can go to the website to reconstruct it. Please note - you will need to enter the information exactly as it was entered before to recreate the same Unique ID.

PPMI

1 3 2

INCLUSION/EXCLUSION - PARKINSON DISEASE (Amend 4)

1 0

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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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.

PPMI

1 3 2

INCLUSION/EXCLUSION - PARKINSON DISEASE (Amend 4)

1 0

SUBJECT ID

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VISIT NO

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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 levodopa 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.

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PROTOCOL DEVIATION CODE

PPMI

1 3 2

INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)

1 1

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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MM

DD

YYYY

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 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.

PPMI

1 3 2

INCLUSION/EXCLUSION - HEALTHY CONTROL (Amend 4)

1 1

SUBJECT ID

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VISIT NO

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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.

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PROTOCOL DEVIATION CODE

PPMI

1 3 2

INCLUSION/EXCLUSION - SWEDD (Amend 4)

8 6

SUBJECT ID

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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.
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.
11. Confirmation from imaging core that screening dopamine transporter SPECT scan is consistent with no dopamine transporter deficit (or for sites only conducting PET scan that VMAT-2 PET scan shows no evidence of VMAT deficit). 11.

To be **ELIGIBLE** for study participation **ALL** answers to items 1-5 , 7, 8 and 11 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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INCLUSION/EXCLUSION - SWEDD (Amend 4)

8 6

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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 levodopa 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.

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PROTOCOL DEVIATION CODE

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INCLUSION/EXCLUSION - PRODROMAL (Amend 5)

1 0

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

6. Confirmation from imaging core that screening dopamine transporter SPECT scan 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
 - c.) Written confirmation or documentation from testing facility that the individual is LRRK2 mutation positive

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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INCLUSION/EXCLUSION - PRODROMAL (Amend 5)

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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**

PPMI

AV-133 ELIGIBILITY

1 3 2

1 1

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- A. Check box if subject signed consent to participate in the ¹⁸F-AV-133-PPMI companion protocol.
- B. Date informed consent for participation in ¹⁸F-AV-133-PPMI companion protocol was signed:
- B.

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- MM DD YYYY

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

1. Women of childbearing potential must be using effective method of birth control 14 days prior to until at least 24 hours after injection of ¹⁸F-AV-133. 1.

To be **ELIGIBLE** for study participation item 1 must be 1 = YES if female of childbearing potential

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

1. Current clinically significant cardiovascular disease or clinically important abnormalities on Screening ECG (including but not limited to QTc > 450 msec), prior to the first ¹⁸F-AV-133 injection. 1.
2. Currently taking medications that are known to cause QT-prolongation. 2.
3. Currently taking tetrabenazine (TBZ) or amphetamine type medications. 3.
4. Received any of the following medications that might interfere with PET imaging: neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine or amphetamine derivative, within 2 weeks of the Screening ¹⁸F-AV-133 injection. 4.
5. Current clinically significant endocrine or metabolic disease, pulmonary, renal or hepatic impairment, or cancer (excluding localized basal cell carcinoma and in situ prostate cancer) that would interfere with completion of the study. 5.
6. Have had prior intracranial surgery that would be expected to alter imaging. 6.

To be **ELIGIBLE** for study participation **ALL** answers to items 1-6 must be **0 = No**

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TELEPHONE FOLLOW-UP

1 2

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INSTRUCTIONS: To be used for Interim Telephone call to subject.1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. 1a. If No (0), please indicate the reason: 1a.

1 = phone disconnected

2 = multiple messages left on answering machine were not returned

3 = subject moved - unable to locate

5 = other (specify) _____

If new contact information obtained for the subject (e.g., change of phone number or address) document the new contact information in the subject's study record and Confidential Subject Identification Log.

During the telephone contact:

- Review and record concomitant medications
- Review and record adverse events

2. Comments:

PPMI

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PD FEATURES

1 4

SUBJECT ID

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1. Date of first symptom onset per the subject:

1.

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 MM YYYY2a. Date of Parkinson's disease diagnosis:
(Leave blank if patient has a diagnosis
other than PD.)2a.

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 MM DD YYYY2b. 1 = Actual (ACT), 2 = Day Estimated (Day), 3 = Mon/Day Est. (MD),
4 = Month Est. (Mon)2b.

3. Were the following symptoms present at the time of diagnosis? (0 = No, 1 = Yes, U = Unknown)

3a. Resting Tremor

3a.

3b. Rigidity

3b.

3c. Bradykinesia

3c.

3d. Postural instability

3d.

3e. Other, specify: _____

3e.

4. Side predominantly affected at onset (1 = Left, 2 = Right, 3 = Symmetric)

4.

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PRIMARY DIAGNOSIS

1 6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

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2. Most likely primary diagnosis:

2.

01 = Idiopathic PD

02 = Alzheimer's disease

03 = Chromosome-17 frontotemporal dementia

04 = Corticobasal degeneration

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 illness

16 = Vascular parkinsonism

17 = No PD nor other neurological disorder

18 = Spinocerebellar Ataxia (SCA)

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

Examiner

STAFF CODE

1 3 2

PPMI
FAMILY HISTORY (PD)

2 0

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYYNUMBER of
FAMILY MEMBERSNUMBER with PD or
PARKINSONISM

1. Biological Mother	1.1 <input type="text"/> 1	1.2 <input type="text"/>
2. Biological Father	2.1 <input type="text"/> 1	2.2 <input type="text"/>
3. Full Siblings	3.1 <input type="text"/> <input type="text"/>	3.2 <input type="text"/> <input type="text"/>
4. Half Siblings	4.1 <input type="text"/> <input type="text"/>	4.2 <input type="text"/> <input type="text"/>
5. Maternal Grandparents	5.1 <input type="text"/> 2	5.2 <input type="text"/>
6. Paternal Grandparents	6.1 <input type="text"/> 2	6.2 <input type="text"/>
7. Maternal Aunts and Uncles	7.1 <input type="text"/> <input type="text"/>	7.2 <input type="text"/> <input type="text"/>
8. Paternal Aunts and Uncles	8.1 <input type="text"/> <input type="text"/>	8.2 <input type="text"/> <input type="text"/>
9. Children	9.1 <input type="text"/> <input type="text"/>	9.2 <input type="text"/> <input type="text"/>

MEDICAL HISTORY (GENERAL)

1 3 2

1 8

SUBJECT ID

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NOTE: This form starts with question 1d.

1. Has the subject ever had a significant disorder, disease or surgery of the following systems?

CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
1d. Dermatological History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		
1e. Ophthalmological History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		
1f. ENT History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		

SUBJECT ID

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CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
Pulmonary History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		
Cardiovascular History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		
Gastrointestinal History? <input type="checkbox"/>	1.		
	2.		
	3.		
	4.		

SUBJECT ID VISIT NO

CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
1j. Hepatobiliary History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1k. Renal History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1l. Gynecologic/ Urologic History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

SUBJECT ID

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VISIT NO

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CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
1m. Musculoskeletal History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1n. Metabolic/ Endocrine History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1o. Hemato/Lymphatic History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

SUBJECT ID VISIT NO

CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
1p. Neurologic (other than disease under study) History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1q. Psychiatric History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		
1r. Allergy/ Immunologic Please note drug allergies History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

SUBJECT ID VISIT NO

CATEGORIES	Enter all significant medical history items, including history from birth to present. Specify disorder/diagnosis and onset. For surgeries, specify reason/diagnosis. Use only one line per description. If more than 4 items, enter in 'Additional Information' category and indicate which category the condition falls under. DO NOT ABBREVIATE.	1 = Active 2 = Resolved	Year of Diagnosis
1s. Other History? <input type="checkbox"/> (0 = None, 1 = Yes)	1.		
	2.		
	3.		
	4.		

Additional Information

If there are more than 4 medical history items per category, enter in 'Additional information' category below. Indicate which category the condition falls under (e.g., 1a, 1b, etc.). **DO NOT ABBREVIATE.**

Category			
<input type="checkbox"/> <input type="checkbox"/>	A.		
<input type="checkbox"/> <input type="checkbox"/>	B.		
<input type="checkbox"/> <input type="checkbox"/>	C.		
<input type="checkbox"/> <input type="checkbox"/>	D.		
<input type="checkbox"/> <input type="checkbox"/>	E.		
<input type="checkbox"/> <input type="checkbox"/>	F.		
<input type="checkbox"/> <input type="checkbox"/>	G.		

PPMI

1 3 2

GENERAL NEUROLOGICAL EXAM

2 2

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Cranial Nerves

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

- | | | | | |
|-----|-------------|--|-----|--------------------------|
| 1a. | I | | 1a. | <input type="checkbox"/> |
| | | | | |
| 1b. | II | | 1b. | <input type="checkbox"/> |
| | | | | |
| 1c. | III, IV, VI | | 1c. | <input type="checkbox"/> |
| | | | | |
| 1d. | V | | 1d. | <input type="checkbox"/> |
| | | | | |
| 1e. | VII | | 1e. | <input type="checkbox"/> |
| | | | | |
| 1f. | VIII | | 1f. | <input type="checkbox"/> |
| | | | | |
| 1g. | IX, X | | 1g. | <input type="checkbox"/> |
| | | | | |
| 1h. | XI | | 1h. | <input type="checkbox"/> |
| | | | | |
| 1i. | XII | | 1i. | <input type="checkbox"/> |
| | | | | |

Motor System

2. Muscle Strength

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

- | | | | | |
|-----|-----------|--|-----|--------------------------|
| 2a. | RIGHT ARM | | 2a. | <input type="checkbox"/> |
| | | | | |
| 2b. | LEFT ARM | | 2b. | <input type="checkbox"/> |
| | | | | |
| 2c. | RIGHT LEG | | 2c. | <input type="checkbox"/> |
| | | | | |
| 2d. | LEFT LEG | | 2d. | <input type="checkbox"/> |
| | | | | |

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3. Coordination

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

Finger-to-nose

3a. RIGHT HAND _____ 3a. 3b. LEFT HAND _____ 3b.

Heel-to-shin

3c. RIGHT LEG _____ 3c. 3d. LEFT LEG _____ 3d.

Sensory

4. Sensation (pain, light touch, position, vibration)

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

4a. RIGHT ARM _____ 4a. 4b. LEFT ARM _____ 4b. 4c. RIGHT LEG _____ 4c. 4d. LEFT LEG _____ 4d.

Reflexes

5. Muscle Stretch Reflexes

0 = Absent, 1 = Hypoactive, 2 = Normal, 3 = Hyperactive, no clonus, 4 = Hyperactive, clonus,

5 = Not tested, 6 = Unable to test

If response is 5 or 6, describe briefly.

5a. RIGHT ARM _____ 5a. 5b. LEFT ARM _____ 5b. 5c. RIGHT LEG _____ 5c. 5d. LEFT LEG _____ 5d.

6. Plantar Response

0 = Flexor, 1 = Extensor, 2 = Indeterminate, 3 = Not tested, 4 = Unable to test

If response is 3 or 4, describe briefly.

6a. RIGHT _____ 6a. 6b. LEFT _____ 6b.

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STAFF CODE

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ORGAN SYSTEM ABNORMALITIES BY EXAMINATION

Use the following Key for items 1-11:

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

1. Skin

1.

2. Head/Neck/Lymphatic

2.

3. Eyes

3.

4. Ears/Nose/Throat

4.

5. Lungs

5.

SUBJECT ID

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ORGAN SYSTEM ABNORMALITIES BY EXAMINATION

Use the following Key for items 1-11:

0 = Normal, 1 = Abnormal (If abnormal, describe briefly), 2 = Not tested, 3 = Unable to test

6. Cardiovascular (including peripheral vascular)

6.

7. Abdomen

7.

8. Musculoskeletal

8.

9. Neurological

9.

10. Psychiatric

10.

11. Other (Specify location and describe.)

11.

PPMI**VITAL SIGNS**

1 3 2

2 6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYY

-
1. Weight (in Kilograms) - Baseline and Annual only 1. .
 2. Height (in Centimeters) - Baseline and Annual only 2.
 3. Temperature (in Celsius) 3. .
 4. Arm used to measure blood pressure? (1 = Right arm, 2 = Left arm) 4.
 5. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for
1-3 minutes) 5. /
 6. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 6.

 9. Standing blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been standing for
1-3 minutes) 9. /
 10. Standing heart rate (beats per minute)
(to be taken after subject has been standing for 1-3 minutes) 10.
 11. Comments:

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PREGNANCY FORM

2 8

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1. If female, was pregnancy test performed?

(0 = No, 1 = Yes)

If No, specify in comments.

1.

- 1a. If the response to question 1 is Yes, is the subject pregnant?

(0 = No, 1 = Yes)

1a.

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

(0 = No, 1 = Yes, 2 = Not Applicable) If No, specify in comments.

1b.

NOTE: If pregnant, consult protocol.

2. Comments:

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CLINICAL DIAGNOSIS AND MANAGEMENT QUESTIONNAIRE

8 8

SUBJECT ID

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4. Has there been a change in the clinical diagnosis of this subject since the last visit? 4.
(0 = No, 1 = Yes)

If Yes (1) to question 4, indicate all factors that have been most influential in your current diagnosis: (0 = No, 1 = Yes)

- 4a. Dopamine transporter imaging information 4a.
- 4b. Clinical signs 4b.
- 4c. Response/lack of response to PD medication 4c.
- 4d. Natural history of condition (i.e. rapid progression, lack of progression) 4d.
- 4e. Other (specify) _____ 4e.

5. Has there been a change in the clinical management of this subject since the last visit? (0 = No, 1 = Yes) 5.

6. Current management for this subject includes: (0 = No, 1 = Yes)

- 6a. Management aimed at treating symptoms of PD, including dopamine replacement therapy, anticholinergics, MAO-B inhibitor 6a.
- 6b. Enrolled in a treatment trial for PD 6b.
- 6c. Management aimed at treating a condition other than PD or PS not associated with a dopamine transporter deficit 6c.
- 6d. Additional diagnostic testing 6d.
- 6e. No treatment necessary 6e.

7. Has the subject seen another neurologist since the last visit? (0 = No, 1 = Yes) 7.

- 7a. If yes, what is that neurologist's working diagnosis?
(specify) _____

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DIAGNOSTIC FEATURES (PD)

1 7

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Factors Suggesting a Diagnosis: Questions below are based on the **INVESTIGATOR's** opinion.

Which of the following features are present and therefore might have an impact on the correct diagnosis?

Answer 0 = No or 1 = Yes for each item.

- | | |
|--|------------------------------|
| 1. Excessive stroke risk factors (e.g., diabetes, hypertension, cardiovascular disease) or past symptoms suggestive of cerebrovascular disease | 1. <input type="checkbox"/> |
| 2. Unusual or atypical risk factors, exposure, or past history (e.g., drug exposure, acute or chronic toxin exposure, acute infection preceding parkinsonism, repeated head trauma, boxer) | 2. <input type="checkbox"/> |
| 3. Unusual or atypical presenting features or symptoms | 3. <input type="checkbox"/> |
| 4. Unusual or atypical course of disease: | |
| 4.1 Very rapid progression | 4.1 <input type="checkbox"/> |
| 4.2 Static or little change | 4.2 <input type="checkbox"/> |
| 4.3 Hemiparkinsonism longer than 6 years | 4.3 <input type="checkbox"/> |
| 4.4 Onset before age 30 | 4.4 <input type="checkbox"/> |
| 4.5 Other, specify: _____ | 4.5 <input type="checkbox"/> |

Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

- | | |
|---|------------------------------|
| 5. Tremor: | |
| 5.1 Resting tremor present and typical for PD | 5.1 <input type="checkbox"/> |
| 5.2 Resting tremor absent | 5.2 <input type="checkbox"/> |
| 5.3 Prominent action tremor | 5.3 <input type="checkbox"/> |
| 5.4 Other, specify: _____ | 5.4 <input type="checkbox"/> |
| 6. Rigidity: | |
| 6.1 Rigidity is present and typical for PD | 6.1 <input type="checkbox"/> |
| 6.2 Rigidity is absent | 6.2 <input type="checkbox"/> |
| 6.3 Axial rigidity in excess of distal rigidity | 6.3 <input type="checkbox"/> |
| 6.4 Marked unilateral or asymmetric rigidity | 6.4 <input type="checkbox"/> |
| 6.5 Additional type of increased tone (i.e., paratonia, mitgehen, spasticity) | 6.5 <input type="checkbox"/> |
| 6.6 Other, specify: _____ | 6.6 <input type="checkbox"/> |

PPMI

1 3 2

DIAGNOSTIC FEATURES (PD)

1 7

SUBJECT ID VISIT NO

Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

7. Akinesia/Bradykinesia:
- 7.1 Bradykinesia is present and typical for PD 7.1
 - 7.2 Bradykinesia is absent 7.2
 - 7.3 Pure Akinesia (without rigidity or tremor) 7.3
 - 7.4 Bradykinesia does not completely account for difficulty with rapid successive movements (e.g., apraxia, ataxia, pyramidal tract dysfunction) 7.4
 - 7.5 Other, specify: _____ 7.5
8. Postural or gait disturbances:
- 8.1 Postural and gait disturbances are completely typical of PD 8.1
 - 8.2 Wide-based gait or ataxia 8.2
 - 8.3 Prominent freezing early in course 8.3
 - 8.4 Likely to fall if not extra careful 8.4
 - 8.5 Other, specify: _____ 8.5
9. Mental Changes:
- 9.1 Psychiatric 9.1
 - 9.2 Cognitive 9.2
10. Other hyperkinesias (not related to levodopa or agonists):
- 10.1 Dystonia 10.1
 - 10.2 Chorea 10.2
 - 10.3 Myoclonus (include stimulus-induced) 10.3
 - 10.4 Other (e.g., alien limbs): _____ 10.4
11. Presence of body hemiatrophy 11.
12. Autonomic disturbances:
- 12.1 Postural hypotension 12.1
 - 12.2 Sexual dysfunction 12.2
 - 12.3 Urinary dysfunction 12.3
 - 12.4 Bowel dysfunction 12.4

PPMI

1 3 2

DIAGNOSTIC FEATURES (PD)

1 7

SUBJECT ID

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VISIT NO

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Specific Clinical Features: Answer 0 = No or 1 = Yes for each item.

- | | |
|--|------------------------------|
| 13. Oculomotor disturbances | 13. <input type="checkbox"/> |
| 14. Eyelid disturbances (e.g., "apraxia" of lid opening, blepharospasm) | 14. <input type="checkbox"/> |
| 15. Other neurological abnormalities atypical of parkinsonism (e.g., hyperreflexia, Babinski sign, sensory deficit, amyotrophy, limb apraxia, sleep apnea, dysmetria or other cerebellar dysfunction) | 15. <input type="checkbox"/> |
| 16. Little or no response to levodopa or a dopamine agonist (Enter N if never treated with dopaminergic medications) | 16. <input type="checkbox"/> |
| 17. Presence of very rapid speech (tachyphemia) | 17. <input type="checkbox"/> |
| 18. Presence of dysphagia or other bulbar dysfunction | 18. <input type="checkbox"/> |
| 19. CT is suggestive of another cause of parkinsonism (Enter N if CT not done) | 19. <input type="checkbox"/> |
| 20. MRI is suggestive of another cause of parkinsonism (Enter N if MRI not done) | 20. <input type="checkbox"/> |
| 21. Is there anything unusual or atypical about this subject's disease (e.g., presentation, symptoms, signs, course, response to therapy, etc.) which could indicate an alternative diagnosis to Parkinson's disease (i.e., idiopathic parkinsonism with the presence of Lewy bodies in the substantia nigra), no matter how remote? | 21. <input type="checkbox"/> |

Examiner

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STAFF CODE

PPMI

1 3 2

PRODROMAL DIAGNOSTIC QUESTIONNAIRE

1 5

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

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1. Indicate the current most likely clinical diagnosis from one of the categories listed below (choose one):

1.

- 01 = Idiopathic PD
02 = Alzheimer's disease
03 = Chromosome-17 frontotemporal dementia
04 = Corticobasal degeneration
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 illness
16 = Vascular parkinsonism
17 = No PD nor other neurological disorder
18 = Spinocerebellar Ataxia (SCA)
23 = Prodromal non-motor PD (at least one non-motor symptom and no motor symptoms)
24 = Prodromal motor PD (at least one motor symptom to meet eligibility for enrollment in PPMI as PD subject)
97 = Other neurological disorder(s) (specify) _____

2. To what degree are you confident that this subject has motor signs consistent with a parkinsonian syndrome (PS) (any condition in which there is neurodegeneration of dopaminergic cells in the substantia nigra)?

2.

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

MOTOR ASSESSMENTS/ MDS-UPDRS

PPMI

1 3 2

USE OF PD MEDICATION

3 0

SUBJECT ID

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VISIT NO

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INITIALS

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VISIT DATE

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1. Is the subject on medication for treating the symptoms of Parkinson disease? 1.
(0 = No, 1 = Yes)
2. If yes, what is the subject taking: (check all that apply)
- Levodopa
 - Dopamine Agonist
 - Other

NOTE: Complete Questions 3 - 6 for subjects taking levodopa or dopamine agonist as of Month 12 and/or subsequent annual visit(s). Subject will have full MDS-UPDRS (Part I - IV) assessed off medication, followed by repeat Part III motor exam one hour after dosing in clinic (complete MDS-UPDRS Post Dose worksheet).

3. Was the full MDS-UPDRS assessed at this visit prior to dosing in clinic? 3.
(0 = No, 1 = Yes)
4. Date of most recent PD medication dosing: 4.

--	--

 MM

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 YYYY
5. Time of most recent PD medication dosing prior to full MDS-UPDRS being assessed: (24-hour clock) 5.

--	--

 :

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6. Time that the full MDS-UPDRS was administered prior to dosing in clinic: (24-hour clock) 6.

--	--

 :

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MDS-UPDRS

&

Hoehn & Yahr

MDS-UPDRS Permissions

Permission is required to use the MDS-developed Rating Scales (with the exception of personal/individual use). Reproduction, translation, modification, sale, or distribution of any portion of the MDS Rating Scales is strictly prohibited. MDS Rating Scales may not be incorporated into clinical trials, training or certification programs or materials, software programs, or otherwise except through use of the [Permissions Request Form](#) and payment of applicable fees.

SUBJECT ID

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VISIT NO

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INITIALS

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MM

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YYYY

A. Time of PD medication dosing in clinic: (24-hour clock)

A.

--	--

 :

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B. Time Part III and Hoehn & Yahr administered:

B.

--	--

 :

--	--

3.1 Speech

--

3.10 Gait

--

3.2 Facial expression

--

3.11 Freezing of gait

--

3.3a Rigidity - Neck

--

3.12 Postural stability

--

3.3b Rigidity - RUE

--

3.13 Posture

--

3.3c Rigidity - LUE

--

3.14 Global spontaneity of movement

--

3.3d Rigidity - RLE

--

3.15a Postural tremor - Right hand

--

3.3e Rigidity - LLE

--

3.15b Postural tremor - Left hand

--

3.4a Finger Tapping Right Hand

--

3.16a Kinetic tremor - Right hand

--

3.4b Finger Tapping Left Hand

--

3.16b Kinetic tremor - Left hand

--

3.5a Hand movements - Right Hand

--

3.17a Rest tremor amplitude - RUE

--

3.5b Hand movements - Left Hand

--

3.17b Rest tremor amplitude - LUE

--

3.6a Pronation - Supination Movements - Right Hand

--

3.17c Rest tremor amplitude - RLE

--

3.6b Pronation - Supination Movements - Left Hand

--

3.17d Rest tremor amplitude - LLE

--

3.7a Toe tapping - Right foot

--

3.17e Rest tremor amplitude - Lip/jaw

--

3.7b Toe tapping - Left foot

--

3.18 Constancy of rest

--

3.8a Leg agility - Right leg

--

3.19 Were dyskinesias present No Yes3.8b Leg agility - Left leg

--

3.20 Did these movements interfere with ratings No Yes3.9 Arising from chair

--

3.21 Hoehn and Yahr Stage

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Examiner

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 STAFF CODE

PPMI

1 3 2

MODIFIED SCHWAB & ENGLAND ACTIVITIES OF DAILY LIVING

3 2

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

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YYYY

- 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
(Investigator, patient, other sources)

1.

Examiner

STAFF CODE

NON – MOTOR ASSESSMENTS

HOPKINS VERBAL LEARNING TEST REVISED (HVLT)

Hopkins Verbal Learning Test Permissions

The Hopkins Verbal Learning Test must be purchased from PAR, Inc. (<http://www4.parinc.com>).

PPMI

1 3 2

HOPKINS VERBAL LEARNING TEST - REVISED

3 6

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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YYYY

Record scores below from the HVLT-R Test Booklet.

1. Hopkins Verbal Learning Test - Revised

- | | | | |
|-----|---|------|--|
| 1.1 | Immediate Recall Trial 1 (# correct) | 1. 1 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.2 | Immediate Recall Trial 2 (# correct) | 1. 2 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.3 | Immediate Recall Trial 3 (# correct) | 1. 3 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.4 | Delayed Recall Trial 4 (# correct after 20 minutes delay) | 1. 4 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.5 | Delayed recognition - Total # of true - positive responses ("hits") | 1. 5 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.6 | Delayed recognition - # of <u>related</u> false - positive errors | 1. 6 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |
| 1.7 | Delayed recognition - # of <u>unrelated</u> false - positive errors | 1. 7 | <table border="1" style="display: inline-table; width: 30px; height: 20px;"></table> |

2. Indicate the HVLT-R test booklet used at this visit (if different than indicated in the protocol, comment below):

- Form 1
- Form 2
- Form 3
- Form 4
- Form 5
- Form 6

Comment: _____

BENTON JUDGMENT OF LINE ORIENTATION

Benton Line Orientation Test Permissions

The Benton Judgment of Line Orientation must be purchased from PAR, Inc. (<http://www4.parinc.com>).

PPMI

1 3 2

SEMANTIC FLUENCY

3 8

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYY

-
1. Record the number of animals named in one minute (60 seconds): 1.
 2. Record the number of vegetables named in one minute (60 seconds): 2.
 3. Record the number of fruits named in one minute (60 seconds): 3.

LETTER NUMBER SEQUENCING

Letter Number Sequencing Test Permissions

Permissions for use of the Letter Number Sequencing Test as used in the PPMI study must be requested from Pearson Assessments (<http://www.pearsonassessments.com/pai/>)

SYMBOL DIGIT MODALITIES TEST

Symbol Digit Modalities Test Permissions

Permissions for use of the Symbol Digit Modalities Test as used in the PPMI study must be requested from Western Psychological Services – WPS (<http://portal.wpspublish.com>).

PPMI

1 3 2

SYMBOL DIGIT MODALITIES TEST

4 2

SUBJECT ID

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INITIALS

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VISIT DATE

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MM

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YYYY

1. Total correct (Response should be 0-110)

1.

--	--	--

2. Indicate the form used at this visit (if different than indicated in the protocol, comment below):

- Form 1
 Form 2

Comment: _____

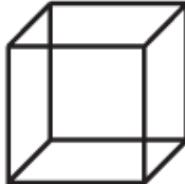
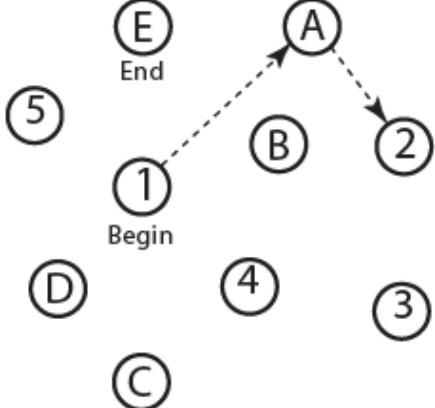
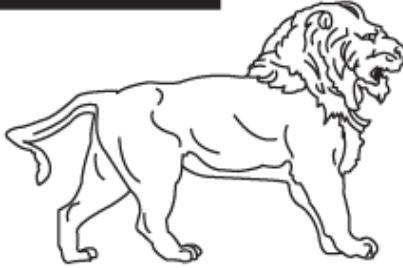
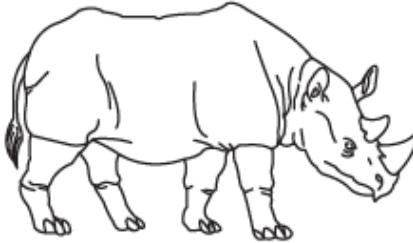
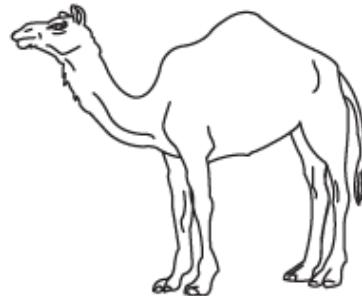
SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

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DD

YYYY

MONTREAL COGNITIVE ASSESSMENT (MOCA)

VISUOSPATIAL / EXECUTIVE			Draw CLOCK (Ten past eleven) (3 points)	POINTS				
 E End A B 2 5 1 Begin D 4 3 C [] []		[]	Contour Numbers Hands	___/5				
NAMING					[] [] [] ___/3			
MEMORY		Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.		FACE VELVET CHURCH DAISY RED	No points			
		1st trial						
		2nd trial						
ATTENTION		Read list of digits (1 digit/sec.). Subject has to repeat them in the forward order Subject has to repeat them in the backward order		[] 2 1 8 5 4 [] 7 4 2	___/2			
Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors [] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B ___/1								
Serial 7 subtraction starting at 100 [] 93 [] 86 [] 79 [] 72 [] 65 4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt ___/3								
LANGUAGE		Repeat: I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []				___/2		
		Fluency / Name maximum number of words in one minute that begin with the letter F [] _____ (N ≥ 11 words)				___/1		
ABSTRACTION		Similarity between e.g. banana - orange = fruit [] train - bicycle [] watch - ruler				___/2		
DELAYED RECALL		Has to recall words WITH NO CUE	FACE []	VELVET []	CHURCH []	DAISY []	Points for UNCUED recall only	___/5
		Category cue						
Optional		Multiple choice cue						
ORIENTATION		[] Date [] Month [] Year [] Day [] Place [] City					___/6	

SUBJECT ID VISIT NO

MONTREAL COGNITIVE ASSESSMENT (MOCA)

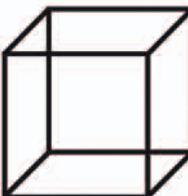
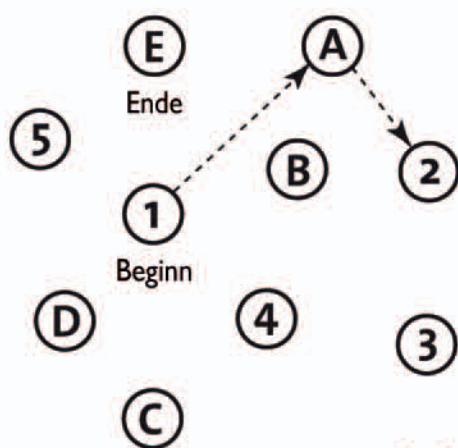
INITIALS SITE NO VISIT DATE

MM

DD

YYYY

VISUOSPATIAL / EXEKUTIV

Würfel
nach-
zeichnenEine Uhr zeichnen (Zehn nach elf)
(3 Punkte)

PUNKTE

[]

[]

[]

[]

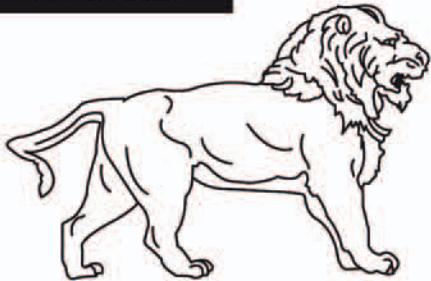
/5

Kontur

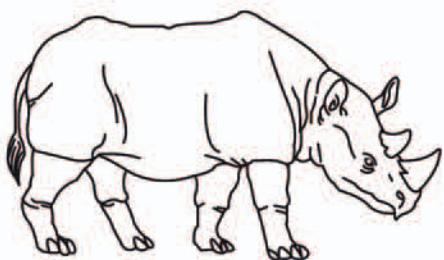
Zahlen

Zeiger

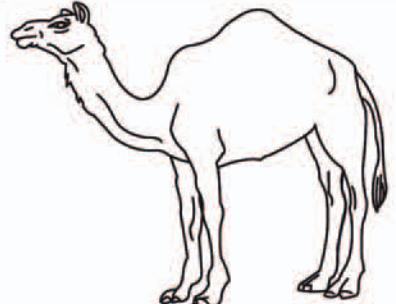
BENENNEN



[]



[]



[]

/3

GEDÄCHTNIS

Wortliste vorlesen, wiederholen lassen.
2 Durchgänge. Nach 5 Minuten überprüfen (s.u.)

GESICHT

SAMT

KIRCHE

TULPE

ROT

Keine
Punkte

1. Versuch

2. Versuch

AUFMERKSAMKEIT

Zahlenliste vorlesen (1 Zahl/ Sek.)

In der vorgegebenen Reihenfolge wiederholen [] 2 1 8 5 4

Rückwärts wiederholen [] 4 3 2 1

/2

Buchstabenliste vorlesen (1 Buchst./Sek.). Patient soll bei jedem Buchstaben „A“ mit der Hand klopfen. Keine Punkte bei 2 oder mehr Fehlern

[] FBACMNAAJKLBAFAKDEAAAJAMOFAAB

/1

Fortlaufendes Abziehen von 7 , mit 100 anfangen [] 93

[] 86

[] 79

[] 72

[] 65

/3

4 oder 5 korrekte Ergebnisse: 3 P., 2 oder 3 korrekt: 2 P., 1 korrekt: 1 P., 0 korrekt: 0 P.

SPRACHE

Wiederholen: „Ich weiß lediglich, daß Horst heute an der Reihe ist zu helfen.“ []

„Die Katze versteckte sich immer unter der Couch, wenn die Hunde im Zimmer waren.“ []

/2

Möglichst viele Wörter in einer Minute benennen, die mit dem Buchstaben F beginnen [] (N ≥ 11 Wörter) /1

ABSTRAKTION

Gemeinsamkeit von z.B. Banane und Apfelsine = Frucht [] Eisenbahn - Fahrrad [] Uhr - Lineal /2

ERINNERUNG

Worte erinnern OHNE HINWEIS [] GESICHT [] SAMT [] KIRCHE [] TULPE [] ROT [] Punkte nur bei richtigem Nennen OHNE Hinweis /5

Optional

Hinweis zu Kategorie [] Mehrfachauswahl [] /5

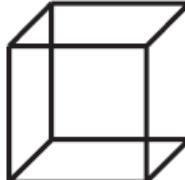
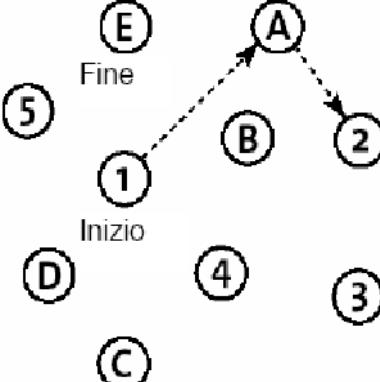
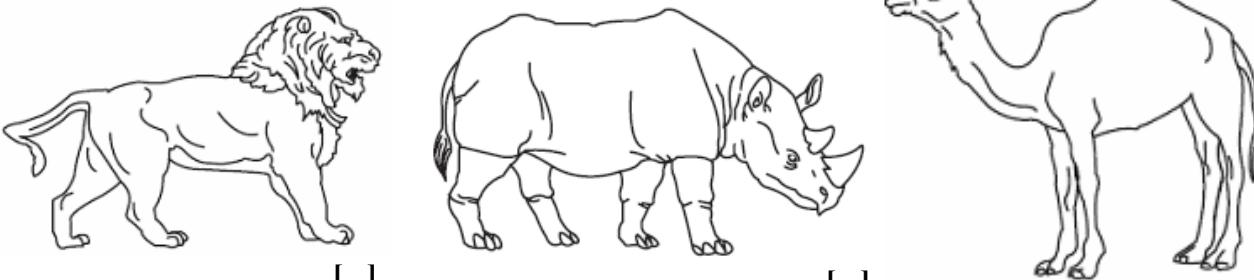
ORIENTIERUNG

[] Datum [] Monat [] Jahr [] Wochentag [] Ort [] Stadt /6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE MM DD YYYY

MONTREAL COGNITIVE ASSESSMENT (MOCA)

- ITALIA -

VISUOSPAZIALE / ESECUTIVO			Copia Il cubo	Disegni un orologio (undici e dieci) (3 punti)			PUNTI		
 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Contorno	<input type="checkbox"/> Numeri	<input type="checkbox"/> Lancette	<u> / 5 </u>		
DENOMINAZIONE									
 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>									
MEMORIA	Leggere la lista di parole: il soggetto deve ripeterle. Fare le prime 2 prove di seguito e il "Richiamo" dopo 5 min.		<input type="checkbox"/>	Faccia	Velluto	Chiesa	Margherita	Rosso	0 punti
			1° prova	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			2° prova	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ATTENZIONE	Leggere la serie di cifre (una cifra / sec.)		Il soggetto deve ripeterle Il soggetto deve ripeterle in ordine inverso						<u> / 2 </u>
			<input type="checkbox"/> 2 1 8 5 4	<input type="checkbox"/> 7 4 2					
Leggere la serie di lettere. Il soggetto deve dare un colpetto con la mano sul tavolo ad ogni lettera "A". 0 punti se 2 errori								<u> / 1 </u>	
[] F B A C M N A A G H L B A F A H D E A A A G A M O F A A B									
Sottrazione di 7 partendo da 100 per 5 volte								[] 93 [] 86 [] 79 [] 72 [] 65	<u> / 3 </u>
4 o 5 sottrazioni corrette: 3 pt, 2 o 3 corrette: 2 pt, 1 corretta: 1 pt, 0 corretta: 0 pt									
LINGUAGGIO	Ripeta: So solo che oggi dobbiamo aiutare Giovanni. Il gatto si nascondeva sempre sotto il divano quando c'erano cani nella stanza.							<input type="checkbox"/> <input type="checkbox"/>	<u> / 2 </u>
Fluenza	In 1 minuto, nomini il maggior numero possibile di parole che iniziano con la lettera "F". [] (N 11 parole)								<u> / 1 </u>
ASTRAZIONE	Similitudini tra per es. banana / arancio = frutti; [] treno / bicicletta [] orologio / righello								<u> / 2 </u>
RICHIAMO DIFFERITO	Deve ricordarsi le parole SENZA AIUTO		Faccia <input type="checkbox"/>	Velluto <input type="checkbox"/>	Chiesa <input type="checkbox"/>	Margherita <input type="checkbox"/>	Rosso <input type="checkbox"/>	Punti solo per ripetizione SENZA AIUTO	<u> / 5 </u>
	AIUTO	Categoria Seman.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Opzionale		Scelta multipla	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
ORIENTAMENTO	[] Data [] Mese [] Anno [] Giorno [] Luogo [] Città								<u> / 6 </u>
© Z. Nasreddine. Traduzione a cura di A. Pirani, C. Tulipani, M. Neri. Versione 26 Luglio 2006								Normale: 61 26 / 30	TOTALE <u> / 30 </u>
								Aggiungere 1 punto se ≤ 12 anni di istruzione	

PPMI

EPWORTH SLEEPINESS SCALE

1 3 2

4 4

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE

MM

DD

YYYY

A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver

A.

How likely are you to doze off or fall asleep in situations described below, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

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

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

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

REM SLEEP DISORDER QUESTIONNAIRE

SUBJECT ID

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A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver

A.

1. I sometimes have very vivid dreams. (0 = No, 1 = Yes)

1. 2. My dreams frequently have an aggressive or action-packed content.
(0 = No, 1 = Yes)2.

3. The dream contents mostly match my nocturnal behaviour. (0 = No, 1 = Yes)

3.

4. I know that my arms or legs move when I sleep. (0 = No, 1 = Yes)

4.

5. It thereby happened that I (almost) hurt my bed partner or myself. (0 = No, 1 = Yes)

5.

6. I have or had the following phenomena during my dreams:

6.1 speaking, shouting, swearing, laughing loudly (0 = No, 1 = Yes)

6.1

6.2 sudden limb movements, "fights" (0 = No, 1 = Yes)

6.2

6.3 gestures, complex movements, that are useless during sleep, e.g., to wave, to salute, to frighten mosquitoes, falls off the bed (0 = No, 1 = Yes)

6.3 6.4 things that fell down around the bed, e.g., bedside lamp, book, glasses
(0 = No, 1 = Yes)6.4

7. It happens that my movements awake me. (0 = No, 1 = Yes)

7.

8. After awakening I mostly remember the content of my dreams well. (0 = No, 1 = Yes)

8.

9. My sleep is frequently disturbed. (0 = No, 1 = Yes)

9.

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10. I have/had a disease of the nervous system: (0 = No, 1 = Yes)

10a. stroke

10a.

10b. head trauma

10b.

10c. parkinsonism

10c.

10d. RLS

10d.

10e. narcolepsy

10e.

10f. depression

10f.

10g. epilepsy

10g.

10h. inflammatory disease of the brain

10h.

10i. other, specify: _____

10i.

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- A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient und caregiver A.
1. Ich habe teilweise sehr lebhafte Träume. (0 = Nein, 1 = Ja) 1.
2. Meine Träume haben des öfteren aggressiven oder aktionsgeladenen Inhalt. (0 = Nein, 1 = Ja) 2.
3. Die Trauminhalte stimmen meist mit meinem nächtlichen Verhalten überein. (0 = Nein, 1 = Ja) 3.
4. Mir ist bekannt, dass ich meine Arme oder Beine im Schlaf bewege. (0 = Nein, 1 = Ja) 4.
5. Es ist dabei vorgekommen, dass ich meinen Partner oder mich selbst (beinahe) verletzt habe. (0 = Nein, 1 = Ja) 5.
6. Bei mir treten oder traten während des Träumens folgende Erscheinungen auf:
- 6.1 laut Sprechen, Schreien, Schimpfen, Lachen (0 = Nein, 1 = Ja) 6.1
- 6.2 plötzliche Bewegungen der Gliedmaßen „Kämpfen“ (0 = Nein, 1 = Ja) 6.2
- 6.3 Gesten, Bewegungsabläufe, die im Schlaf sinnlos sind wie z.B. winken, salutieren, Mücken verscheuchen, Stürze aus dem Bett (0 = Nein, 1 = Ja) 6.3
- 6.4 um das Bett herum umgefallene Gegenstände wie z.B. Nachttischlampe, Buch, Brille (0 = Nein, 1 = Ja) 6.4
7. Es kommt vor, dass ich durch meine eigenen Bewegungen wach werde. (0 = Nein, 1 = Ja) 7.
8. Nach dem Erwachen kann ich mich an den Inhalt meiner Träume meist gut erinnern. (0 = Nein, 1 = Ja) 8.
9. Mein Schlaf ist häufiger gestört. (0 = Nein, 1 = Ja) 9.

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10. Bei mir liegt/lag eine Erkrankung des Nervensystems vor: (0 = Nein, 1 = Ja)

10a. Schlaganfall

10a.	<input type="checkbox"/>
------	--------------------------

10b. Gehirnerschütterung

10b.	<input type="checkbox"/>
------	--------------------------

10c. Parkinson

10c.	<input type="checkbox"/>
------	--------------------------

10d. RLS

10d.	<input type="checkbox"/>
------	--------------------------

10e. Narkolepsie

10e.	<input type="checkbox"/>
------	--------------------------

10f. Depression

10f.	<input type="checkbox"/>
------	--------------------------

10g. Epilepsie

10g.	<input type="checkbox"/>
------	--------------------------

10h. entzündliche Erkrankung des Gehirns

10h.	<input type="checkbox"/>
------	--------------------------

10i. anderes, spezifizieren: _____

10i.	<input type="checkbox"/>
------	--------------------------

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GERIATRIC DEPRESSION SCALE (Short Version)

1 3 2

4 8

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

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Geriatische Depressions-Skala

1. Sind Sie mit Ihrem Leben im Grunde zufrieden? ja/nein
2. Haben Sie viele Ihrer Aktivitäten und Interessen aufgegeben? ja/nein
3. Glauben Sie, daß Ihr Leben sinnlos ist? ja/nein
4. Langweilen Sie sich oft? ja/nein
5. Sind Sie die meiste Zeit über guter Stimmung? ja/nein
6. Fürchten Sie, daß Ihnen etwas Schlechtes zustoßen könnte? ja/nein
7. Fühlen Sie sich die meiste Zeit über glücklich? ja/nein
8. Fühlen Sie sich oft hilflos? ja/nein
9. Bleiben Sie lieber zu Hause, anstatt auszugehen und neue Dinge zu erleben? ja/nein
10. Glauben Sie, daß Sie mit dem Gedächtnis mehr Schwierigkeiten haben als die meisten anderen? ja/nein
11. Finden Sie es wunderbar, jetzt zu leben? ja/nein
12. Fühlen Sie sich unter den jetzigen Umständen als ziemlich wertlos? ja/nein
13. Fühlen Sie sich energiegeladen? ja/nein
14. Halten Sie Ihre Situation für hoffnungslos? ja/nein
15. Glauben Sie, daß es den meisten Menschen besser geht als Ihnen? ja/nein

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SCÁLA DI AUTOVALUTAZIONE EMOZIONALESI NO

1. È fondamentalmente soddisfatto della Sua vita?
2. Le è capitato spesso di abbandonare alcune delle sue attività e/o interessi?
3. Pensa che la Sua vita sia vuota?
4. È spesso annoiato?
5. È spesso di buon umore?
6. Ha paura che Le stia per capitare qualcosa di brutto?
7. È felice di solito?
8. Le capita spesso di sentirsi debole ed indifeso?
9. Preferisce stare a casa piuttosto che uscire?
10. Crede di avere più problemi degli altri con la memoria?

11. Pensa che sia bello essere vivi?
12. Le sembra di vivere senza scopo?
13. Si sente pieno di energia?
14. Si sente in una situazione senza speranza?
15. Pensa che la maggior parte della gente stia meglio di Lei?

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**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

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

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

STATE-TRAIT ANXIETY INVENTORY

State-Trait Anxiety Inventory Test Permissions

The State-Trait Anxiety Inventory must be purchased from Mind Garden (<http://www.mindgarden.com>).

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A. Source of Information: 1 = Patient, 2 = Caregiver, 3 = Patient and caregiver

A.

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SCOPA-AUT

By means of this questionnaire, we would like to find out to what extent in the past month you have had problems with various bodily functions, such as difficulty passing urine, or excessive sweating. Answer the questions by placing a cross in the box which best reflects your situation. If you wish to change an answer,

fill in the 'wrong' box and place a cross in the correct one. If you have used medication in the past month in relation to one or more of the problems mentioned, then the question refers to how you were while taking this medication. You can note the use of medication on the last page.

1. In the past month have you had difficulty swallowing or have you choked?

never

sometimes

regularly

often

2. In the past month, has saliva dribbled out of your mouth?

never

sometimes

regularly

often

3. In the past month, has food ever become stuck in your throat?

never

sometimes

regularly

often

4. In the past month, did you ever have the feeling during a meal that you were full very quickly?

never

sometimes

regularly

often

5. *Constipation is a blockage of the bowel, a condition in which someone has a bowel movement twice a week or less.*

In the past month, have you had problems with constipation?

never

sometimes

regularly

often

6. In the past month, did you have to strain hard to pass stools?

never

sometimes

regularly

often

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7. In the past month, have you had involuntary loss of stools?

never

sometimes

regularly

often

Questions 8 to 13 deal with problems with passing urine. If you use a catheter you can indicate this by placing a cross in the box "use catheter".

8. In the past month, have you had difficulty retaining urine?

never

sometimes

regularly

often

use
catheter

9. In the past month, have you had involuntary loss of urine?

never

sometimes

regularly

often

use
catheter

10. In the past month, have you had the feeling that after passing urine your bladder was not completely empty?

never

sometimes

regularly

often

use
catheter

11. In the past month, has the stream of urine been weak?

never

sometimes

regularly

often

use
catheter

12. In the past month, have you had to pass urine again within 2 hours of the previous time?

never

sometimes

regularly

often

use
catheter

13. In the past month, have you had to pass urine at night?

never

sometimes

regularly

often

use
catheter

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14. In the past month, when standing up have you had the feeling of either becoming light-headed, or no longer being able to see properly, or no longer being able to think clearly?

never

sometimes

regularly

often

15. In the past month, did you become light-headed after standing for some time?

never

sometimes

regularly

often

16. Have you fainted in the past 6 months?

never

sometimes

regularly

often

17. In the past month, have you ever perspired excessively during the day?

never

sometimes

regularly

often

18. In the past month, have you ever perspired excessively during the night?

never

sometimes

regularly

often

19. In the past month, have your eyes ever been over-sensitive to bright light?

never

sometimes

regularly

often

20. In the past month, how often have you had trouble tolerating cold?

never

sometimes

regularly

often

21. In the past month, how often have you had trouble tolerating heat?

never

sometimes

regularly

often

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The following questions are about sexuality. Although we are aware that sexuality is a highly intimate subject, we would still like you to answer these questions. For the questions on sexual activity, consider every form of sexual contact with a partner or masturbation (self-gratification). An extra response option has been added to these questions. Here you can indicate that the situation described has not been applicable to you in the past month, for example because you have not been sexually active. Questions 22 and 23 are intended specifically for men, 24 and 25 for women.

The following 3 questions are only for men

22. In the past month, have you been impotent (unable to have or maintain an erection)?

never

sometimes

regularly

often

not
applicable

23. In the past month, how often have you been unable to ejaculate?

never

sometimes

regularly

often

not
applicable

- 23a. In the past month, have you taken medication for an erection disorder? (If so, which medication?)

no

yes: _____

Proceed with question 26

The following 2 questions are only for women

24. In the past month, was your vagina too dry during sexual activity?

never

sometimes

regularly

often

not
applicable

25. In the past month, have you had difficulty reaching an orgasm?

never

sometimes

regularly

often

not
applicable

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The following questions are for everyone

26. In the past month, have you used medication for:

a. constipation?

no

yes: _____

b. urinary problems?

no

yes: _____

c. blood pressure?

no

yes: _____

d. other symptoms
*(not symptoms related
to Parkinson's disease)*

no

yes: _____

© This questionnaire is made available free of charge, with the permission of the authors, to all those undertaking non-profit and profit making research. Future users may be requested to share data for psychometric purposes. Use of this questionnaire in studies should be communicated to the developers. No changes may be made to the questionnaire without written permission. Please use the following reference in publications:

Visser M, Marinus J, Stiggelbout AM, van Hilten JJ. Assessment of autonomic dysfunction in Parkinson's disease: The SCOPA-AUT. Mov Disord. 2004;19:1306-12.

For further information, please contact M.Visser, Leiden University Medical Center, Department of Neurology (K5Q), P.O. Box 9600, NL-2300 RC Leiden (email: m.visser@lumc.nl).

OLFACtORY TESTING

UPSiT Test Permissions

The UPSiT must be purchased from Sensonics, Inc. (<http://www.sensonics.com/shop/pc/home.asp>).

PPMI

1 3 2

UNIVERSITY OF PENNSYLVANIA SMELL ID TEST

5 4

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Record score from each booklet.

1. Score from booklet #1:

2. Score from booklet #2:

3. Score from booklet #3:

4. Score from booklet #4:

5. Comments:

PPMI

1 3 2

COGNITIVE CATEGORIZATION

5 3

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A. Indicate the source of information:

1 = Subject, 2 = Caregiver, 3 = Subject and Caregiver

A. **Determining Report of Cognitive Decline**

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a decline in cognition compared with pre-morbid abilities (i.e., pre-PD). The following cognitive abilities should be considered:

Attention: Ability to sustain and direct attention, lapses

Memory: Registration, recall of recent events or important dates, new learning ability, misplacement of items, forgetting items

Orientation: Forgetting appointments, estimating time, spatial or geographical orientation

Executive abilities: Reasoning ability, making decisions, following instructions, difficulty with calculations

Praxis: Constructional or mechanical cognitive ability, such as use of tools and appliances

Language: Word finding problems, problems with naming or comprehension

1. Has the subject experienced cognitive decline? (0 = No, 1 = Yes)

1. **Determining Functional Impairment**

Based on information provided by the subject, the informant, and/or based on the Site Investigator's judgment, determine whether the subject has experienced a significant decline in functional abilities (from a cognitive standpoint) to the extent of demonstrating impairment in performing instrumental activities of daily living, examples of which include: driving, managing finances, managing medications, shopping, food preparation, participation in hobbies and employment.

2. Does the subject have clinically significant functional impairment as a result of cognitive impairment? (0 = No, 1 = Yes)

2.

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Determining Cognitive Diagnosis

Based on your impression of the subject's current cognitive function, which may include performance on neuropsychological testing, as well as your knowledge of his/her pre-morbid cognitive function and the degree to which cognitive deficits impact his/her ability to carry out daily activities, please rate the subject's current cognitive status. The determination of dementia implies (1) cognitive function that is impaired in more than one cognitive domain, (2) decline from pre-morbid function, and (3) significant impact of cognitive impairment on daily function. The determination of MCI is based on (1) impairment in at least one cognitive domain, (2) decline from pre-morbid function, and (3) lack of significant impact of cognitive impairment on daily function.

3. Based on your clinical impression, which of the following categories best describes the subject's cognitive state: 3.
- 1 = Normal Cognition (PD-NC)
2 = Mild Cognitive Impairment (PD-MCI)
3 = Dementia (PDD)
4. What is your level of confidence of this cognitive diagnosis? 4.
- 1 = 90 - 100%
2 = 50 - 89%
3 = 10 - 49%
4 = 0 - 9%
5. Did you review any neuropsychological tests (including MoCA scores) in making this determination? (0 = No, 1 = Yes) 5.

IMAGING ASSESSMENTS

PPMI

1 3 2

MAGNETIC RESONANCE IMAGING

6 0

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1. MRI scan: (0 = Not Completed, 1 = Completed)
If Not Completed (0), provide reason in Comments.

1.

1a. Date MRI scan completed:

1a.

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1b. Did MRI scan include DTI sequences? (0 = No, 1 = Yes)

1b.

1c. Did MRI scan include resting state sequences? (0 = No, 1 = Yes)

1c.

2. MRI data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes)

2.

3. MRI scan results (based on radiologist interpretation) are: (Baseline Only)

3.

1 = Normal

2 = Abnormal, not clinically significant

3 = Abnormal, clinically significant (specify in Comments)

Comments:

NOTE: DTI sequences at Baseline and annual visits performed at select sites only.

PPMI**DaTSCAN IMAGING**

1 3 2

6 2

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1. SPECT imaging scan: (0 = Not Completed, 1 = Completed)
If Not Completed (0), provide reason in Comments.

1.

1a. Date SPECT scan was completed:

1a.

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1b. Location where SPECT scan was completed? (1 = Site, 2 = IND)

1b.

1c. Injection: (1 = DaTSCAN, 2 = Beta-CIT)

1c.

2. SPECT imaging data transferred to the core imaging lab at Institute for Neurodegenerative Disorders: (0 = No, 1 = Yes)

2.

3. SPECT Visual Interpretation Report indicates the scan is (Screening only):

3.

1 = Consistent with evidence of dopamine transporter deficit

2 = Not consistent with evidence of dopamine transporter deficit

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

Comments:

PPMI**AV-133 IMAGING**

1 3 2

6 3

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VITAL SIGNS MEASURED APPROXIMATELY 5 MINUTES PRIOR TO INJECTION

1. Time vital signs measured prior to injection: (24 hour clock) 1.

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2. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for
1-3 minutes) 2.

			/			
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3. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 3.

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4. If female of childbearing potential, was serum pregnancy test performed
(Screening Only)? (0 = No, 1 = Yes) 4.

 - 4a. Indicate the result of the serum pregnancy test:
0 = Negative
1 = Positive 4a.

 - 4b. Was the result of the serum pregnancy test confirmed prior to the first
¹⁸F-AV-133 injection? (0 = No, 1 = Yes) 4b.

5. If female of childbearing potential, was urine pregnancy test performed?
(0 = No, 1 = Yes) 5.

 - 5a. Indicate the result of the urine pregnancy test:
0 = Negative
1 = Positive 5a.

 - 5b. Was the result of the urine pregnancy test confirmed prior to ¹⁸F-AV-133
injection? (0 = No, 1 = Yes) 5b.

6. Time of ¹⁸F-AV-133 injection: (24 hour clock) 6.

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PPMI**AV-133 IMAGING**

1 3 2

6 3

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VITAL SIGNS MEASURED APPROXIMATELY 15 MINUTES POST-INJECTION

7. Time vital signs measured after ¹⁸F-AV-133 injection: (24 hour clock) 7.

--	--	--

 :

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8. Supine blood pressure: systolic/diastolic (mmHg)
(to be taken after subject has been supine for
1-3 minutes) 8.

				/			
--	--	--	--	---	--	--	--
9. Supine heart rate (beats per minute)
(to be taken after subject has been supine for 1-3 minutes) 9.

--	--	--	--
10. AV-133 PET imaging scan: (0 = Not Completed, 1 = Completed) 10.

--
- 10a. Date AV-133 PET imaging scan
was completed: 10a.

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11. AV-133 imaging data transferred to the core imaging lab at Institute for
Neurodegenerative Disorders: (0 = No, 1 = Yes) 11.

--
12. VMAT-2 PET Visual Interpretation Report indicates the scan is (Screening only): 12.

--

1 = Consistent with vesicular monoamine transporter (VMAT-2) deficit
2 = Not consistent with vesicular monoamine transporter (VMAT-2) deficit

Note: Women of childbearing potential must have a negative urine and serum pregnancy test result **prior to** the screening imaging scan and must have a negative urine pregnancy test result **prior to** injection of a follow up imaging scan.

Comments:

BIOSPECIMEN SAMPLES

PPMI**CLINICAL LABS**

1 3 2

5 9

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

1.

1a. Date shipped to central lab:

1a.

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Comments:

PPMI**DNA SAMPLE**

1 3 2

5 6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYY

1. Blood sample for DNA: (0 = Not Collected, 1 = Collected)

1.

1a. Date blood sample for DNA collected:

1a.
MM DD YYYY

2. Volume of blood collected: (milliliters)

2.

3. Date DNA sample shipped:

3.
MM DD YYYY

PPMI

1 3 2

WHOLE BLOOD SAMPLE

7 8

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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MM

DD

YYYY

1. Whole blood for storage and analysis: (0 = Not collected, 1 = Collected)

1.

1a. Date of whole blood collection:

1a.

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MM

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DD

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YYYY

2. Comments:

PPMI

1 3 2

LABORATORY PROCEDURES

5 8

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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MM

DD

YYYY

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1. Date of last intake of food:

1.

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MM

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DD

YYYY

1a. Time of last intake of food: (24-hour clock)

1a.

--	--

 :

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1b. Fasting status:

(1 = Fasted (minimum of 8 hours), 2 = Low Fat Diet, 3 = Not Fasted, No Low Fat Diet)

1b.

--

2. Is subject on medication for PD? (0 = No, 1 = Yes)

2.

--

2a. Date of most recent PD medication dosing:

2a.

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MM

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DD

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YYYY

2b. Time of most recent PD medication dosing: (24-hour clock)

2b.

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Urine Sample Collection

3. Urine for storage and analysis: (0 = Not collected, 1 = Collected)

3.

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3a. Date of urine sample collection:

3a.

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MM

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DD

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YYYY

3b. Time of urine sample collection: (24-hour clock)

3b.

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3c. Time of centrifugation: (24-hour clock)

3c.

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3d. Rate of centrifugation: (xg)

3d.

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3e. Duration of centrifugation: (minutes)

3e.

--	--

3f. Indicate temperature at which tube was spun: (Celsius)

3f.

--	--

3g. Time urine sample placed in freezer: (24-hour clock)

3g.

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SUBJECT ID VISIT NO **Blood Sample Collection**

4. Date blood samples collected:

4. MM DD YYYY**(RNA – PAXgene RED TOP)**

5. Blood for PAXgene/RNA: (0 = Not collected, 1 = Collected)

5. 5a. Time of PAXgene/RNA sample collection:
(24-hours at room temperature)5a. : 5b. Date PAXgene/RNA samples placed in
freezer:5b. MM DD YYYY

5c. Time PAXgene/RNA samples placed in freezer:

5c. :

5d. Storage temperature: (Celsius)

5d. - **(PLASMA – EDTA PURPLE TOP)**

6. Blood for plasma: (0 = Not collected, 1 = Collected)

6.

6a. Time of plasma sample collection: (24-hour clock)

6a. :

6b. Time of centrifugation: (24-hour clock)

6b. :

6c. Rate of centrifugation: (xg)

6c.

6d. Duration of centrifugation: (minutes)

6d.

6e. Indicate temperature at which tube was spun: (Celsius)

6e.

6f. Total volume aliquotted after spinning: (milliliters)

6f. .

6g. Total number of aliquot tubes:

6g.

6h. Time plasma samples placed in freezer: (24-hour clock)

6h. :

6i. Storage temperature: (Celsius)

6i. -

SUBJECT ID VISIT NO **(SERUM – RED TOP)**

7. Blood for serum: (0 = Not collected, 1 = Collected)

7.

7a. Time of serum sample collection: (24-hour clock)

7a. :

7b. Time of centrifugation: (24-hour clock)

7b. :

7c. Rate of centrifugation: (xg)

7c.

7d. Duration of centrifugation: (minutes)

7d.

7e. Indicate temperature at which tube was spun: (Celsius)

7e.

7f. Total volume aliquotted after spinning: (milliliters)

7f. .

7g. Total number of aliquot tubes:

7g.

7h. Time serum samples placed in freezer: (24-hour clock)

7h. :

7i. Storage temperature: (Celsius)

7i. -

Comments:

PPMI**LUMBAR PUNCTURE**

1 3 2

6 4

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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MM

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DD

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YYYY

A. Date of last intake of food:

A.

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MM

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DD

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YYYY

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

B.

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Ba. Fasting status:

(1 = Fasted (minimum of 8 hours), 2 = Low Fat Diet, 3 = Not Fasted,
No Low Fat Diet)Ba.

--

C. Is subject on medication for PD? (0 = No, 1 = Yes)

C.

--

Ca. Date of most recent PD medication dosing:

Ca.

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MM

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DD

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YYYY

Cb. Time of most recent PD medication dosing (24-hour clock)

Cb.

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1. Lumbar puncture for collection of CSF:

(0 = Not Done, 1 = Collected, 2 = Partial Collection, 3 = Attempted, no collection)
If response is 0, 2 or 3, specify in comments.1.

--

2. Date CSF collected:

2.

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MM

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DD

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YYYY

3. 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

3.

--

PPMI**LUMBAR PUNCTURE**

1 3 2

6 4

SUBJECT ID

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VISIT NO

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4. Indicate method of collecting the CSF:

4.

1 = Gravity

2 = Syringe suction

5. Lumbar puncture performed at the:

5.

0 = L2-L3 Interspace

1 = L3-L4 Interspace

2 = L4-L5 Interspace

3 = Unknown

6. Subject position when lumbar puncture performed:

6.

1 = Sitting, leaned over (preferred)

2 = Lying, curled up on side

3 = Unknown

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

7.

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8. Volume of CSF collected prior spinning: (milliliters)

8.

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9. Time CSF was centrifuged: (24-hour clock)

9.

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(Within 15 minutes from sample collection)

10. Rate of centrifugation for the CSF sample: (xg)

10.

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11. Temperature at which CSF tube was spun: (Celsius)

11.

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12. Time CSF sample aliquotted: (24-hour clock)

12.

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13. Total volume of CSF aliquotted after spinning: (milliliters)

13.

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14. Total number of aliquot tubes:

14.

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15. Was part of sample discarded due to a bloody tap? (0 = No, 1 = Yes)

15. 16. Time samples were either placed in freezer or placed on dry ice:
(24-hour clock)16.

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16a. Storage temperature if placed in freezer: (Celsius)

16a. -

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17. Was part of the sample sent to local lab for analyses? (0 = No, 1 = Yes)
If No, specify in Comments.17.

PPMI**LUMBAR PUNCTURE**

1 3 2

6 4

SUBJECT ID

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VISIT NO

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18. What is the white blood cell count?

18.

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18b. Indicate units:

 Per cubic millimeter Per microliter Per liter Other _____

19. What is the red blood cell count?

19.

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19b. Indicate units:

 Per cubic millimeter Per microliter Per liter Other _____

20. What is the total protein?

20.

			.		
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20a. Indicate units: mg/dL g/dL g/L

21. What is the total glucose?

21.

			.		
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21a. Indicate units: mg/dL mmol/L

22. Was a fluoroscopy performed? (0 = No, 1 = Yes)

22.

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22a. Date of fluoroscopy:

22a.

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MM

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DD

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YYYY

23. Was a lumbar spine film performed? (0 = No, 1 = Yes)

23.

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23a. Date of spine film:

23a.

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MM

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DD

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YYYY

Comments:

LOGS & FORMS

**CONCLUSION of STUDY
SIGNATURE FORM
TRANSFER
CONCOMITANT MEDICATION
CURRENT MEDICAL CONDITIONS
ADVERSE EVENT**

PPMI

SIGNATURE FORM

1 3 2

6 6

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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MM

DD

YYYY

NOTE: a signature form is required for each expected study visit and telephone contact whether or not the visit or call was actually performed.

1.1 Visit Completion Status: (Include comment for any answer other than 1 or 7 under question 3, Comments.) 1.1

- 1 = Within visit window and conducted by investigator (or coordinator if telephone contact).
- 2 = Within visit window and not conducted by investigator.
- 3 = Not done (If visit not done enter the target visit date in the header).
- 4 = Out of visit window and conducted by investigator (or coordinator if telephone contact).
- 5 = Out of visit window and not conducted by investigator.
- 6 = Unscheduled Visit
- 7 = Other (specify) _____

1.2 Indicate why the subject missed the visit. 1.2

- 1 = Scheduling issue with the subject.
- 2 = Scheduling issue with the staff.
- 3 = Family/social issues with the subject.
- 4 = Subject did not return phone calls to schedule study visit.
- 5 = Travel Distance
- 6 = Medical Problems
- 7 = Military Duty
- 8 = Financial Issues
- 9 = Lost to Follow up (complete Conclusion of Study Participation form).
- 10 = Other: _____
- 11 = Institutionalized

13 = Replaced by Symptomatic Therapy Visit

1.3 Were all assessments for this visit completed? (0 = No, 1 = Yes) 1.3
If No (0), please note assessments not completed in question 3, Comments.

In addition to the assessments covered by the CRFs specific to this visit, the following tasks were completed at this visit when applicable:

2.1 Status of Concomitant Medication Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported taking any concomitant medications; log is blank) 2.1

2.2 Status of Adverse Event Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported any events; log is blank) 2.2

PPMI**SIGNATURE FORM**

1 3 2

6 6

SUBJECT ID

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VISIT NO

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- 2.10 Reviewed Current Medical Conditions Log information and made any necessary changes to the Current Medical Conditions Log: (1 = Updated log at this visit, 2 = No data updates to log; log is not blank, 3 = Subject has not reported any medical conditions; log is blank)

2.10

3. Comments:

I have reviewed the data entries for this visit and determined that they are complete, accurate, and consistent with source documents, if available. All entries were made by me, or by a person who is under my supervision.

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INVESTIGATOR'S SIGNATURE

DATE

STAFF CODE

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COORDINATOR'S SIGNATURE

DATE

STAFF CODE

PPMI

CONCOMITANT MEDICATION LOG

7 | 2

1 | 3 | 2

SUBJECT ID

INITIALS

SITE NO

Enter all medications taken at Screening Visit. At subsequent visits record new meds, and changes/discontinuation of previously listed meds. Changes in total daily dose or route require a new line. Row: enter 1, 2, 3, etc. Medication: Record generic name; if unknown, enter brand name. For multiple ingredient medications, indicate strength if possible, e.g., carbidopa/levodopa 25/100. Dose: Record dose for each administration. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. Ongoing: Answer yes if medication is still being taken at end of study. Indication: Reason for use, not drug category.

SAMPLE	MEDICATION (List generic name, if possible)	DOSE	ROUTE	START DATE (MM/DD/YYYY)	STOP DATE (MM/DD/YYYY)	INDICATION	ONGOING			
							1 = Actual (ACT) 2 = Day Est. (Day) 3 = Month Est. (MD) 4 = Month Est. (MON)	1 = No 0 = Yes	1 = No 0 = Yes	1 = No 0 = Yes
0	paroxetine hydrochloride	20 mg	qd	10/30/2003	2	depression	0	0	0	0

PPMI

1 3 2

CONCLUSION OF STUDY PARTICIPATION

7 4

SUBJECT ID VISIT NO F N LINITIALS SITE NO VISIT DATE

MM

DD

YYYY

2. Did the subject complete the study? (00 = No, 01 = Yes)

2.

If subject prematurely withdrew:

4.

4. What was the primary reason for withdrawal:

01 = Adverse Event (complete AE Log)

02 = Lost to Follow-up

03 = Subject withdrew consent (specify in 4a)

04 = Pregnancy

05 = Protocol violation

06 = Death of subject

07 = Investigator decision (specify in 4a)

09 = Clinical Monitor decision (specify in 4a)

10 = Sponsor decision (specify in 4a)

11 = Primary Care Physician decision (specify in 4a)

12 = Informant/Caregiver decision (specify in 4a)

13 = Institutionalized

14 = Inability to continue giving consent

15 = Other (specify in 4a)

4a. Specify: _____

5. Date of premature withdrawal:

(Date investigator deemed the subject would no longer participate in the study)

5.
MM
DD
YYYY

PPMI

1 | 3 | 2

6 8

ADVERSE EVENT LOG

SUBJECT ID | | |

INITIALS

1

Record all adverse events that occur during the study visit or the 7 day follow up period following an LP or DaTSCAN. Record disease entity as AE **only** if it worsens beyond what investigator expects is within normal range of fluctuation for this subject. Elicit adverse event data by asking an open-ended question, e.g., "What unusual symptoms or medical problems have you experienced since the last visit?" Record any new or change in ongoing sign or symptom as well as any event that has resolved since last evaluation. Enter each change in "severity" on new line. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. IF EVENT IS A SERIOUS ADVERSE EVENT, please refer to the Operations Manual for reporting guidance.

* If 3, 4 or 5 are selected, complete "Related to Study Procedure".

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INVESTIGATOR'S SIGNATURE

DATE

STAFF CODE

PPMI

1 3 2

SUBJECT SITE TRANSFER FORM

7 6

SUBJECT ID VISIT NO INITIALS SITE NO VISIT DATE
MM DD YYYY**NOTE: To be completed by the new site.**

1. Date of re-consent:

1.
MM DD YYYY

2. Transferring site number:

2.

PPMI (TAP-PD) Schedule of Activities

PARKINSON DISEASE (PD) SUBJECTS

Visit Description	Visit Number Months (± 30 days)	Level #	BL	V01	V02	V04	TAPFNL
			0	3	6	12	
Subject Eligibility	78	X					
OPDM Use Questionnaire	80		X				
OPDM Assessment	82	X	X	X	X		
Conclusion of Study Participation	84						X

7/8/2011

PPMI (TAP-PD)

1 3 2

SUBJECT ELIGIBILITY

7 8

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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MM

DD

YYYY

A. Check box if subject has signed consent.

B. Date informed consent was signed:

B.

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MM DD YYYY

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

1. PD subject who is otherwise eligible for enrollment into PPMI. 1.
2. Enrolled at one of three participating sites:
 - Oregon Health Sciences University, Portland, OR
 - Institute for Neurodegenerative Disorders, New Haven, CT
 - University of Pennsylvania Movement Disorders Center, Philadelphia, PA2.
3. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 3.
4. Willing and able to complete additional study procedures. 4.

To be **ELIGIBLE** for study participation **ALL** answers to items 1-4 must be 1 = Yes.

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

1. Evidence of "atypical" parkinsonian syndromes (e.g. Progressive supranuclear palsy, Multiple system atrophy, drug-induced parkinsonism, Lewy body dementia). 1.
2. Any medical condition other than PD that would interfere with the subject's ability to perform study procedures as determined by the investigator. 2.

To be **ELIGIBLE** for study participation **ALL** answers to items 1 and 2 must be 0 = No.

ENROLLMENT

1. Date subject was enrolled into TAP-PD: 1.

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MM DD YYYY
2. Indicate the serial number of the OPDM device sent home with the subject. 2.

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PPMI (TAP-PD)

1 3 2

OPDM USE QUESTIONNAIRE

8 0

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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MM

DD

YYYY

Please respond to the questions below to tell us about your experience with the use of the OPDM home dexterity device.

1. How hard was it to understand the directions for using the OPDM dexterity device? 1.
0 = Not at all hard to understand
1 = A little bit hard to understand
2 = Moderately hard to understand
3 = Very hard to understand
2. How confident were you that you were doing the tasks correctly? 2.
0 = Not at all confident
1 = A little bit confident
2 = Moderately confident
3 = Very confident
3. Did doing the OPDM dexterity tasks at home fit into your regular schedule? 3.
0 = It was easy to fit into my day
1 = I had a little trouble fitting it into my day
2 = It was moderately difficult to fit into my day
3 = It was very difficult to fit into my day
4. Did you need to be reminded (by family members or study staff) to complete the OPDM dexterity device tasks? 4.
0 = Not at all
1 = Rarely (1 or 2 times)
2 = Sometimes (3 - 5 times)
3 = Often (more than 5 times)
5. Did doing the OPDM dexterity tasks at home change the way you felt about participating in the main PPMI study? 5.
0 = Felt a lot more negative
1 = Felt a little more negative
2 = No change
3 = Felt a little more positive
4 = Felt a lot more positive

PPMI (TAP-PD)

132

OPDM ASSESSMENT

8 2

SUBJECT ID

VISIT NO

INITIALS

SITE NO

VISIT DATE

MM

DD

1

- | | | |
|-----|--|---|
| 1. | Was the OPDM assessment completed at this visit?
(0 = No, 1 = Yes) | 1. <input type="checkbox"/> |
| 2. | Indicate the serial number of
the OPDM device used for this subject. | 2. <input type="text"/> |
| 3. | Were the following tasks completed for the OPDM assessment?
(If "No", indicate in Comments) | |
| 3.1 | Digitography (keyboard test) (0 = No, 1 = Yes) | 3.1 <input type="checkbox"/> |
| 3.2 | Paced Keyboard Test (0 = No, 1 = Yes) | 3.2 <input type="checkbox"/> |
| 3.3 | Pegboard (0 = No, 1 = Yes) | 3.3 <input type="checkbox"/> |
| 4. | Was the OPDM data that was collected at this visit transferred to Kinetics?
(0 = No, 1 = Yes) (If "No", indicate in Comments) | 4. <input type="checkbox"/> |
| 5. | Date the OPDM data for this visit was
transferred to Kinetics: | 5. <input type="text"/> <input type="text"/>
MM <input type="text"/> <input type="text"/>
DD <input type="text"/> <input type="text"/> <input type="text"/>
YYYY |
| 6. | Comments: | |

PPMI (TAP-PD)

1 3 2

CONCLUSION OF STUDY PARTICIPATION

8 4

SUBJECT ID VISIT NO T A P F N LINITIALS SITE NO VISIT DATE
MM DD YYYY

2. Did the subject complete the study? (00 = No, 01 = Yes)

2.

If subject prematurely withdrew:

5. Date of premature withdrawal:
(Date investigator deemed the subject would
no longer participate in the study)5.
MM
DD YYYY



Smell Test Self Reporting Questionnaire (SRQ)

Participant Information:

First name of person participating in this study and completing smell test: _____

Date of Birth: Year (YYYY): _____ Month: _____ Calendar Day (1-31): _____

Which Racial Category best describes you:

- American Indian/Alaskan native
- Asian
- Native Hawaiian/Pacific Islander
- Black or African American
- White/ Caucasian
- Other/Unknown

If Other specify: _____

- I prefer not to respond

Which Ethnic Category best describes you:

- Hispanic or Latino
- Not Hispanic or Latino
- I prefer not to respond

Please note: Ethnicity and racial information is being collected to meet research participant protection requirements

Self Report Study Questions:

The following questions will provide important information for evaluating the sense of smell and its relationship to neurological disorders such as Parkinson disease. Please answer all of the questions to the best of your ability.

1. Do you have a diagnosis of Parkinson disease or Parkinsonian syndrome?

YES NO UNSURE

2. Which family members (if any) have Parkinson disease/PD or Parkinsonism (check all that apply):

- Biological mother
- Biological father
- Full sibling/s
- Half sibling/s
- Maternal Grandparents
- Paternal Grandparents
- Maternal Aunts and Uncles
- Paternal Aunts and Uncles
- Children
- I have no known first degree relatives with Parkinson disease
- Unsure





Self Report Study Questions page 2:

The following questions will provide important information for evaluating the sense of smell and its relationship to neurological disorders such as Parkinson disease. Please answer all of the questions to the best of your ability.

3. In the past year have you used laxatives or stool softeners regularly for 3 months or longer?

YES NO UNSURE

4. What is your usual number of bowel movements per day?

- Less than once per day
- Once every other day
- Once per day
- Two per day
- Three per day
- More than three per day

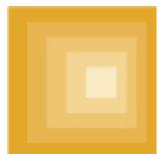
5. Have you noticed a decrease in your sense of smell over the last year?

YES NO UNSURE

6. Have you ever been told, or suspected yourself, that you seem to 'act out your dreams' while asleep (for example: punching, flailing your arms in the air, making running movements, etc)?

YES NO UNSURE





Selbstbericht-Fragebogen zum Riechtest (SRQ)

Angaben zum Teilnehmer:

Vorname und Nachname der Person, die an dieser Studie teilnimmt und den Riechtest durchführt:

Geburtsdatum: Jahr (JJJJ): _____ Monat: _____ Tag (1-31): _____

Welche demographische Kategorie beschreibt Sie am besten:

- Indianer oder Ureinwohner Alaskas (Eskimo/Inuit)
- Asiatisch
- Hawaiianer/Pazifikinsulaner
- Schwarzer oder Afro-Amerikaner
- Weiß/Caucasian (Europäer)
- Sonstige/Unbekannt

Falls sonstige, bitte angeben: _____

- Ich möchte keine Angabe machen

Welche ethnische Kategorie beschreibt Sie am besten:

- Hispanoamerikaner oder Latino
- Nicht Hispanoamerikaner oder Latino
- Ich möchte keine Angabe machen

Zur Beachtung: Angaben zur Ethnizität und Rasse werden erhoben, um die Anforderungen zum Schutz von Studienteilnehmern zu erfüllen.

Selbstbericht-Studienfragen:

Die folgenden Fragen geben uns wichtige Informationen zur Beurteilung des Geruchssinns und seiner Beziehung zu neurologischen Störungen wie Parkinsonkrankheit. Bitte beantworten Sie alle Fragen so gut Sie können.

1. Wurde bei Ihnen Parkinsonkrankheit oder Parkinsonsyndrom diagnostiziert?

JA NEIN NICHT SICHER

2. Welche Familienmitglieder haben (ggf.) Parkinsonkrankheit oder Parkinson-Syndrom (alle zutreffenden Angaben ankreuzen):

- Biologische Mutter
- Biologischer Vater
- Vollgeschwister
- Halbgeschwister
- Großeltern mütterlicherseits
- Großeltern väterlicherseits
- Tanten und Onkel mütterlicherseits
- Tanten und Onkel väterlicherseits
- Kinder
- Ich habe keine bekannten Verwandten ersten Grades mit Parkinson
- Nicht sicher





Selbstbericht-Studienfragen, Seite 2:

Die folgenden Fragen geben uns wichtige Informationen zur Beurteilung des Geruchssinns und seiner Beziehung zu neurologischen Störungen wie Parkinsonkrankheit. Bitte beantworten Sie alle Fragen so gut Sie können.

3. Haben Sie im letzten Jahr Abführmittel oder Stuhlweichmacher regelmäßig über einen Zeitraum von 3 Monaten oder länger verwendet?

JA NEIN NICHT SICHER

4. Wie viele Stuhlgänge haben Sie in der Regel pro Tag?

- Weniger als ein Stuhlgang pro Tag
- Ein Stuhlgang jeden zweiten Tag
- Ein Stuhlgang pro Tag
- Zwei Stuhlgänge pro Tag
- Drei Stuhlgänge pro Tag
- Mehr als drei Stuhlgänge pro Tag

5. Haben Sie im Verlauf des letzten Jahres eine Verringerung Ihres Geruchssinns bemerkt?

JA NEIN NICHT SICHER

6. Wurde Ihnen jemals gesagt, oder haben Sie selbst vermutet, dass Sie während des Schlafs scheinbar „Ihre Träume ausleben“? (Zum Beispiel: Schlagen, mit den Armen in der Luft herumfuchteln, Laufbewegungen machen etc.)

JA NEIN NICHT SICHER





Questionario di autovalutazione per il test olfattivo

Informazioni sul Partecipante:

Nome proprio della persona che partecipa a questo studio e che si sottopone al test olfattivo: _____

Data di nascita: anno (AAAA): _____ mese: _____ giorno (1-31): _____

Quale categoria razziale La descrive meglio?

- Asiatico
- Nero
- Bianco/ Caucasio
- Altro/Sconosciuto

Se altro, specificare: _____

- Preferisco non rispondere

Nota: Le informazioni relative all'appartenenza etnica o razziale vengono raccolte per soddisfare i requisiti per la protezione dei partecipanti alla ricerca

Domande dello studio di autovalutazione

Le domande seguenti forniranno importanti informazioni per valutare il senso dell'olfatto e il suo rapporto con disturbi neurologici, quali la malattia di Parkinson. La preghiamo di rispondere a tutte le domande al meglio delle Sue capacità.

1. Le è stata diagnosticata la malattia di Parkinson?

SI NO NON SONO SICURO

2. Quali membri della Sua famiglia (se ve ne sono) sono affetti dalla malattia di Parkinson (MP) o da parkinsonismo (spuntare la voce corrispondente):

- Madre biologica
- Padre biologico
- Fratelli o sorelle
- Fratellastri o sorellastre
- Nonni materni
- Nonni paterni
- Zii e zie materni
- Zii e zie paterni
- Figli
- Non sono a conoscenza di parenti di primo grado affetti da malattia di Parkinson
- Non sono sicuro





Domande dello studio di autovalutazione, pagina 2:

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La preghiamo di rispondere a tutte le domande al meglio delle Sue capacità.

3. Lo scorso anno ha fatto uso di lassativi o di farmaci per la stitichezza con regolarità per tre mesi o più?
- SI NO NON SONO SICURO

4. Qual'è il numero abituale di defecazioni (movimenti intestinali) al giorno?
- Meno di una al giorno
 Una volta al giorno
 Due volte al giorno
 Tre volte al giorno
 Più di tre volte al giorno

5. Si è accorto di una riduzione del senso dell'olfatto nel corso dell'ultimo anno?
- SI NO NON SONO SICURO

6. Le è mai stato detto - o ha sospettato Lei stesso - di dare l'impressione di "recitare i Suoi sogni" mentre dorme (ad esempio, menando pugni, agitando convulsamente le braccia, accennando una corsa, ecc.)?

SI NO NON SONO SICURO

