

**PD-DOC Protocol Synopsis  
Mayo Clinic Jacksonville**

Protocol Number	763-94 04
Protocol Title	“Movement Disorders Registry at Mayo Clinic Jacksonville”
Acronym/Title	N/A
Clinical Phase and Funding	NINDS – UDALL Center of Excellence
Investigators	Ryan Uitti, M.D., Zbigniew Wszolek, M.D., Jay Van Gerpen, M.D., William Cheshire, M.D. and Tanis Ferman, Ph.D {Research Coordinators: Jennifer Lash, Audrey Strongosky, and Laura Brown}
Study Centers	Mayo Clinic Jacksonville.
Study Period	The patient will be in the registry as long as the patient is under the care of a movement disorder specialist at Mayo Clinic Jacksonville.
Study Objectives	This study is being done to establish a registry for the study of movement disorders to include clinical, genetic and pathological information.
Study Population	Movement disorder patients seen at Mayo Clinic Jacksonville
Study Design	Patients will be consented, provide a blood sample, have the option of participating in Mayo Clinic Jacksonville’s Parkinson’s disease and other related disorders brain bank, and provide clinical information which will be deposited with the PD-DOC database. The patient can agree to be re-evaluated every 1-3 years.
Number of Subjects	50 first year and 25 for each subsequent year
Main Eligibility / Exclusion Criteria	Eligibility: Men or Women over the age of 18 with a diagnosed Movement Disorder
Route and Dosage Form	Not Applicable
Dosage	Not Applicable
Duration of Treatment	Not Applicable
Primary Outcome Measure(s)	To create a registry of movement disorders to include clinical (longitudinal), genetic and pathological information.
Secondary Outcome Measure	Not Applicable

# Mayo Clinic Jacksonville

## Clinical Research Schedule of Activities Incorporating the CORE DS

	Visit 1 BL Week 0 (Day 0)	Visit 2 (12m – 24m)	Visit 3 (24m-36m)	Visit 4 (36m-48m)
<b>Signed Informed Consent</b>	<b>X</b>			
<b>Eligibility Criteria</b>	<b>X</b>			
<b>“Include other study specific evaluations”</b>				
Demographics (Form 02)	<b>X</b>			
Primary Diagnosis <sup>1</sup> (Form 04)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
PD Features (Form 06)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Diagnostic Features <sup>1</sup> (Form 08)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Family History <sup>1</sup> (Form 10)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Mini-Environmental Risks Questionnaire for PD-Baseline (MERQ-PD-B) (Form 12)	<b>X</b>			
Unified Parkinson’s Disease Rating Scale UPDRS Part I (Form 16)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
UPDRS Part II (Form 18)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
UPDRS Part III (Form 20)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
UPDRS Part IV <sup>2</sup> (Form 22)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Modified Hoehn & Yahr Scale (Form 24)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Modified Schwab & England ADL Scale (Form 26)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Cognition/Behavior Questionnaire <sup>1</sup> (Form 28)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Mini Mental State Exam (MMSE) <sup>3</sup> (Form 30)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Hopkins Verbal Learning Test <sup>3</sup> (Form 32)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Verbal Fluency (Controlled Oral Word Association Test [COWAT]) (Form 34)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Letter-Number Sequencing Test (LNST) <sup>3</sup> (Form 36)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Geriatric Depression Scale (GDS-15) <sup>4</sup> (Form 38)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Neuropsychiatric Inventory Questionnaire (NPI-Q) <sup>5</sup> (Form 40)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Specimen Collection (Form 42) DNA Blood Sampling for the NINDS Human Genetics Repository (Coriell)	<b>X</b>			
Signature Form (Form 44)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
NACC Neuropathology Data Form <sup>6</sup> Version 9 (Form 46)				
Supplemental Neuropathology Form <sup>6</sup> (Form 48)				
PD Medication Log (Form 50)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<b>Subject Conclusion</b>				

<sup>1</sup> To be completed by an expert clinician.

<sup>4</sup> Self-report form.

<sup>2</sup> To be completed on all subjects even those not taking PD medications. <sup>5</sup> To be completed during an interview with the Caregiver.

<sup>3</sup> Due to copyright restrictions, form to be provided by the PD-DOC.

<sup>6</sup> To be completed by an expert neuropathologist.

Complete the CORE DS at least every 3 years, excluding forms 02, 12, and 42.