

**Udall Center of Excellence
Johns Hopkins University**

PROTOCOL SYNOPSIS

Longitudinal Study of PD and Related Disorders

Protocol Number	JHU IRB:98-05-08-06
Protocol Title	Longitudinal Study of PD and Related Disorders
Acronym/Title	N/A
Clinical Phase and Funding	NIH
Investigators	Laura Marsh, Jason Brandt, Cynthia Munro, Ted Dawson, Frederick Lenz, Stephen Grill, Elizabeth O' Hearn, Susan Bassett, Melissa Gerstenhaber, Juan Troncoso, Rebecca Dunlop, James Williams, Gay Rudow, Gregory Pontone {Research Coordinator: Leah Swearingin and consent designee} {Consent Designees: Elaina Hirsch, Justine Palanci }
Study Centers	1-Johns Hopkins University
Study Period	Longitudinal 7/09
Study Objectives	The primary aim of this protocol is to recruit and characterize patients with Parkinson's disease (PD) and a cohort of controls without CNS disease and follow their motor, cognitive, and psychiatric features longitudinally on a biennial basis until ultimate death. A second component of the protocol includes registration as a prospective brain donor, so that, at the time of their death, subjects who are followed longitudinally have their brain tissue submitted for autopsy and basic research on PD. There are also individuals who register only as prospective brain donors, and medical records are retrieved with their permission and placed in their file. A third component of the protocol enables subjects to be included in a database registry that includes individuals who provide permission to be contacted regarding participation in future studies and medical records and other study records are retrieved with their permission and placed in their file.
Study Population	People with PD and controls.
Study Design	Provide a brief summation of the design of the study using information regarding blinding, dosage escalation, length of study, treatment course, patient groups, etc.
Number of Subjects	300.

Main Eligibility / Exclusion Criteria	<p><u>Parkinson's Disease and Related Disorders</u></p> <p><u>Inclusion Criteria:</u> Diagnosis of Idiopathic PD or diagnosis of parkinsonian related disorders, men and women over age 21.</p> <p><u>Exclusion Criteria:</u> Other CNS disease, e.g. significant head injury, repeated strokes, current alcohol or substance abuse.</p> <p><u>Controls:</u></p> <p><u>Inclusion Criteria:</u> Men and women over age 21</p> <p><u>Exclusion Criteria-Controls:</u> Current alcohol or substance abuse, repeated strokes or other CNS disease, history of head injury.</p>
Route and Dosage Form	N/A
Dosage	N/A
Duration of Treatment	N/A
Primary Outcome Measure(s)	To identify, recruit, characterize clinically, and follow longitudinally until death patients with idiopathic Parkinson's Disease (PD) and healthy controls that consent to eventual autopsy, thereby providing material for the Neuropathology Core and neuropathologic studies.. Clinical characterization will involve assessment of the motor, cognitive, and psychiatric features of PD. Comparable assessments will be conducted on controls.
Secondary Outcome Measure	Provide a brief description of any Secondary Outcome(s).
Sample Size Considerations	Briefly describe any Sample Size (power) issues or considerations.
Steering Committee Members	N/A