

**Morris K. Udall Parkinson's Disease Research Center of Excellence
Parkinson's Disease and Movement Disorders Center, Pennsylvania Hospital
University of Pennsylvania**

PRECIS

Parkinson's Disease Clinical Database

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| Protocol Number | 800864 |
| Protocol Title | Parkinson's Disease Clinical Database |
| Acronym/Title | Udall Core |
| Clinical Phase and Funding | NIH/NINDS |
| Investigators | Andrew Siderowf, MD, MSCE Howard Hurtig, MD |
| Study Center | Parkinson's Disease and Movement Disorders Center at Pennsylvania Hospital (<i>part of the University of Pennsylvania Health System</i>) |
| Study Period | Longitudinal, anticipated end date 2015 |
| Study Objectives | To determine the functional consequences of cognitive impairment in patients with Parkinson's Disease |
| Study Population | People with PD/PDD and their care partners |
| Study Design | This is a longitudinal study that will follow patients for at least seven years, seeing and assessing patients every 12 ± 2 months. Patients will be asked to participate in optional and ancillary studies geared toward the mission of the Udall Center to identify early diagnosis, assess cognitive dysfunction and its impact on daily living, and treatment for patients with Parkinson's Disease and Parkinson's Disease with Dementia. |
| Number of Subjects | 240 |
| Main Eligibility / Exclusion Criteria | <u>PD/PDD Cohort:</u> <u>Inclusion Criteria:</u> Diagnosis of Parkinson's disease with at least two of the three cardinal features, Parkinson's Disease with Dementia, or diagnosis of parkinsonian-related disorders, men and women over age 60. <u>Exclusion Criteria:</u> Other CNS disease, e.g. significant head injury, repeated strokes, current alcohol or substance abuse, severe anxiety or mood disorders that would prevent accurate neurocognitive assessments, patients who's caregivers are not willing to participate. |
| Duration of Participation | Neurocognitive and motor assessments will be conducted every year. Home visits are offered to patients who are unable to come to the clinic. |

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| Primary Outcome Measure(s) | To identify, recruit, characterize clinically, and follow longitudinally until death patients with Parkinson's Disease (PD) and Parkinson's Disease with Dementia (PDD). Clinical characterization will involve assessment of the motor, cognitive, and psychiatric features of PD. |
| Secondary Outcome Measure | <p>Patients will be offered participation in the Brain Bank at the UPenn CNDR, which further the examination of the pathology of PD and provide tissue for future neuropathic and correlative studies.</p> <p>Patients will be asked to have a research lumbar puncture (LP) to obtain cerebrospinal fluid for biomarker and proteomic studies.</p> <p>Patients who participate in the research LP will be surveyed for motivation, anxiety, and decision-making. Participation in these studies is option and will not preclude patients from participating in the main study.</p> |