NINDS Parkinson's Disease Biomarkers Program (PDBP) FAQs

What is the emphasis of this program?

The overall purpose of the NINDS PDBP is to rapidly identify and develop potential biomarkers to improve the efficiency and outcome of Phase II clinical trials and advance therapeutic development for PD. The two recently released FOAs are for discovery projects, whether laboratory based (see **RFA NS-12-010**) or clinical (see **RFA NS-12-011**) for PD diagnostic or progression markers.

Will there be a set of common clinical assessments performed across cohorts?

Yes,

NINDS General CDEs

All "core" General CDE items and forms will be required in the following domains for all subjects:

- Participant/Subject Characteristics (Demographics)
- Participant/Subject History (Medical History and Behavioral History)
- Assessments and Examinations (Physical/Neurological Exam, Vital Signs, Laboratory Tests and Biospecimens/Biomarkers)
- Treatment/Intervention Data (Prior and Concomitant Medications)
- Protocol Experience (Inclusion and Exclusion Criteria, Informed Consent and Enrollment)

NINDS PD Specific CDEs

All "core" and the following "recommended" items and forms will be required in the domains listed below, both for PD subjects and for those at risk for PD (i.e., pre-symptomatic, gene carriers, etc.). Items that are duplicative of those in the General CDEs need not be collected twice.

- Participant/Subject Characteristics (Demographics)
- Participant/Subject History and Family History (Medical History, Family History)
- Assessments and Examinations (MDS-UPDRS, Hamilton Depression and Anxiety Rating Scales, Montreal Cognitive Assessment, Epworth Sleepiness Scale, RBD Screening Questionnaire, and University of Pennsylvania Smell Identification Test)
- Treatment/Intervention Data (PD Medication Log)
- Outcomes and End Points (PDQ-39).
- Additionally, the Schwab and England ADL Scale will be required. .

Where will the biological specimens be curated?

The biospecimens will be banked, stored, and distributed to other researchers via the NINDS Repository.

Is CSF (once a year) mandatory for clinical studies?

Ideally, CSF will be collected yearly, but we realize this may not be possible for all studies proposed.

What are the volumes of biological specimens required?

Ideally, samples will be collected every six months (other than CSF, which ideally can be collected yearly, and DNA, which only needs to be collected once) in the following volumes:

- Plasma/Serum: minimum 6 milliliters
- Whole blood: (for DNA extraction) minimum 6 milliliters (initial visit only)
- Whole blood for other studies minimum 6 milliliters (in addition to that for DNA at initial and also other than initial visits)
- Pax-gene tube (for RNA) minimum 8 milliliters
- CSF: minimum 10 milliliters (local analyses to include cell count, total protein, glucose, submitted to DMR)

Who is managing the Data Management Resource (DMR)?

The PDBP Data Management Resource will be developed by the NIH Center for Information Technology (CIT) under the leadership of Dr. Matt McAuliffe.

PDBP Data Management Resource

Activities that are the sole purview of the DMR include: 1) development of standardized electronic data forms, data formats and software for use across multiple cohorts and projects; 2) development of software to support subject scheduling, site tracking, and facilitation and coordination of de-identified clinical and biospecimen data collection across multiple new and existing cohorts and projects through an easy to use web-based entry system for submitters; 3) quality assurance checks of data entry and collection; 4) development of a user-friendly query system for users to evaluate availability of data and biospecimens within and across PD biomarker projects; 5) development of aggregate data report formats that are user-friendly and supported by well documented data dictionaries; 6) training for both data submitters and data users; 7) coordination of data and biospecimen summary reports and postings in collaboration with the NINDS Repository; and 8) public outreach for data submission and data use. Development of all electronic data entry forms and quality assurance checks of de-identified data will be done by the DMR.