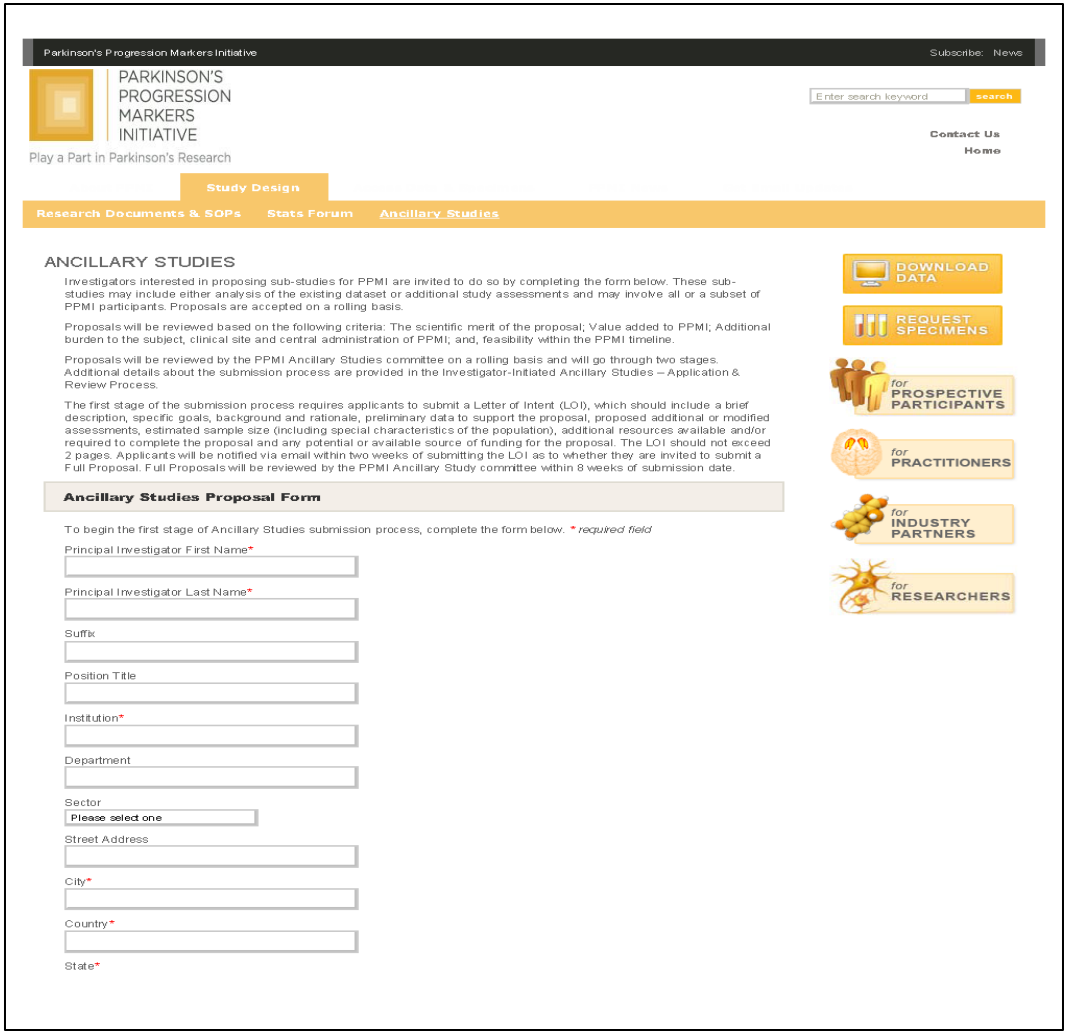
Ancillary Studies

PPMI Ancillary Study Proposals

- Investigators are invited to propose ancillary sub-studies for PPMI
  - initiate the process through the PPMI web site
- These sub-studies may include
  - Analysis of an existing dataset
  - Additional study assessments
  - May involve all or a subset of PPMI participants

PPMI Ancillary Study Proposals

- Easy access e-Form located on PPMI study website
- Straight forward brief process which allows uploading of an ancillary proposal
- Application process is available 24/7 with submissions sent directly to the committee chair



PARKINSON'S PROGRESSION MARKERS INITIATIVE
Play a Part in Parkinson's Research

PPMI Ancillary Study Proposals

- Proposals are accepted on a rolling basis
- Proposals are reviewed on the following criteria
  - The scientific merit of the proposal
  - Value added to PPMI
  - Additional burden to the subject, clinical site and central administration of PPMI
  - Feasibility within the PPMI timeline.

PPMI Ancillary Study Proposal

- Letter of Intent (LOI) 2 pages and includes
  - brief description of the proposed sub-study
  - specific goals
  - background and rationale
  - preliminary data to support the proposal
  - proposed additional or modified assessments
  - estimated sample size (including special characteristics of the population)
  - additional resources available and/or required to complete the proposal
  - any potential or available source of funding for the proposal
- Ancillary Study Committee review of the LOI
  - Notification via email within two weeks of submitting the LOI
    - Yes/No decision; Critique not provided
  - Investigator may be invited to submit a Full Proposal
  - Investigators must identify funding: no funds through PPMI. May apply through established MJFF grant programs or other sponsors.

PPMI Ancillary Study Proposal

- Full Proposals
  - 5 pages in length
  - Follow the format for MJFF research proposals www.michaeljfox.org/research
  - Reviewed by the PPMI Ancillary Study committee (& subject experts as needed) within 8 weeks of submission date
  - No detailed written critique

PPMI Ancillary Study Proposal
Review Criteria

- Consistent with & furthers the overall PPMI goals of developing biomarkers for the progression, prognosis or diagnosis of PD?
- Sufficient preliminary data to justify using PPMI cohort?
- Does not add undue subject burden or detract from the main PPMI protocol
- Expertise, resources and environment of investigator(s)
- Willing to comply with PPMI policies including Publication and Intellectual property
- Data generated from analyses of PPMI data returned; public access

PPMI Ancillary Study Proposal

Committee members:

Sohini Chowdhury
Chris Coffey
Danna Jennings
Shirley Lasch
Ken Marek
Todd Sherer
Andrew Siderowf
Tanya Simuni
Carlie Tanner (Chair)
Eduardo Tolosa

Current Ancillary Studies

- Longitudinal follow-up of screen failure due to scan without dopamine deficit (SWEDD)

- Feasibility and reliability of home dexterity testing using the OPDM-dexterity measure

SWEDD follow up

Primary Objective

To evaluate the probability of a change in the clinical diagnosis of PPMI PD subjects with a baseline DaTSCAN that shows no evidence for DAT deficit (SWEDD)

Secondary Objectives

To compare baseline characteristics of SWEDD to non-SWEDD PD subjects and healthy controls

- clinical characteristics
- biomarker characteristics

To evaluate the change in DAT uptake in the SWEDD subjects over a 24-month period and compare it with change in DAT uptake for PPMI PD subjects

To determine the change in clinical markers over a 24-month period compared to PD patients and normal controls

SWEDD follow up

Subjects

Subjects identified as PD patients for PPMI who are excluded based on a normal DatSCAN at screening

Assessments

24 month follow up: visits at 6 months, 12 months, 18 months (phone) and 24 months

- Clinical (motor, non-motor, neuropsychological)
- Biomic blood draw

DaTSCAN at baseline and 24 months

Home dexterity testing study

Primary objective

To assess the feasibility of incorporating home dexterity testing using the OPDM-Dexterity measure into a longitudinal observational study of progression of Parkinson's disease (PPMI)

Secondary objectives

- To assess the reliability of home dexterity testing over repeated short-term administrations
- To assess the validity of home dexterity testing relative to examiner-based measures (e.g. UPDRS)
- To assess the sensitivity to change of dexterity testing by comparing scores at baseline and year 1.

Home dexterity testing study

Subjects

- 15 PPMI PD subjects at 3 sites (OHSU, INDD, UPenn) total of 45 subjects

Assessments

- Home testing with OPDM dexterity device at least 3 times a month for 3 months
- In person OPDM testing at clinic visits at baseline, 3 months, 6 months and 12 months
- Comparison to UPDRS assessments collected during normal PPMI visits

Current ancillary studies: consistent with review criteria

- Consistent with and furthers the overall goals of PPMI study

- Feasible within parent study
  - Limited additional subject/site burden