PPMI Gait Substudy

Adverse Event In-Clinic Assessment

Complete this form at each visit after completion of the Gait Mobility Assessment to assess for adverse events.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was a Gait Mobility Assessment conducted at this visit?

○ No

○ Yes

1a. If Yes, were adverse events assessed following the procedure?

○ No

○ Yes

i. If No, please explain:

_____

_____

_____

ii. If Yes, were any adverse events observed?

○ No

○ Yes

If question 1.a.ii is "Yes", document information on the Adverse Event Log.

PPMI Gait Substudy

Adverse Event Telephone Assessment

Complete this form for the telephone follow up as per protocol.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was contact made during this telephone call?
   - ○ Yes
   - ○ No

   1a. If no, indicate the reason:
   - ○ Phone disconnected/number no longer in service
   - ○ Messages for participant were not returned
   - ○ Participant moved/unable to locate
   - ○ Other, specify: _____

If no contact is made, ensure that any previously reported adverse event is followed up for resolution.

2. Were any NEW adverse events reported by the participant?
   - ○ No
   - ○ Yes

If question 2 is "Yes", new adverse event(s) should be documented on the Adverse Event Log.

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Conclusion of Study Participation

The *Conclusion of Study Participation* form should be completed when a participant either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Date of conclusion of participation: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

2. Select a reason for conclusion of study participation:
   - ○ Completed study per protocol
   - ○ Transportation/Travel issues (ex: logistics or travel, moved away from study site)
   - ○ Burden of study procedures (other than travel)
   - ○ Family, care-partner, or social issues (such as work/job obligations)
   - ○ Non-compliance with study procedures
   - ○ Adverse event
   - ○ Decline in health
   - ○ Lost to follow up
   - ○ Other, please specify:

     _____

     _____

     _____

     _____

3. Did increasing PD disability contribute to the decision to withdraw from the PPMI Gait Study?
   - ○ No
   - ○ Yes
   - ○ Not Applicable

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Documentation of Informed Consent

Form instructions: Document date participant signed consent as the "Assessment Date" below.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Informed consent was discussed with participant and/or legally authorized representative for the PPMI 009 Gait Study. Participant and/or legally authorized representative was given adequate time to read the informed consent, the opportunity to ask questions and consent was obtained prior to any study procedures being performed.

   ○ No ○ Yes

Monitor responsibilities

- Verify site process for obtaining informed consent is adequate according to 21 CFR 56.109(c) and 28 (21 CFR 50.27).
- Current approved ICF(s) version(s) are signed.
- Informed consent was obtained by person authorized on site delegation log.

PPMI Gait Substudy

Gait Mobility Assessment and Measurement

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Was an Axivity sensor used at this visit?

   ○ Yes

   ○ No, specify: _____

   1a. Indicate serial number of the Axivity sensor: _____

   1b. Provide date Axivity sensor started: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

2. Was Axivity data uploaded and transferred?

   ○ Yes

   ○ No, specify: _____

   2a. Provide date that data was uploaded and transferred: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

3. Were Opal sensors used during this visit?

   ○ Yes

   ○ No, specify: _____

   The following measurements should be taken after placement of the Opal sensors:

   3a. Right arm length in centimeters: _____ (XXX.X) cm

   3b. Left arm length in centimeters: _____ (XXX.X) cm

   3c. Right leg length in centimeters: _____ (XXX.X) cm

   3d. Left leg length in centimeters: _____ (XXX.X) cm

4. Was Gait assessment completed?

   ○ Yes

   ○ No

   4a. Time Gait assessment started: __ __:__ __ (24-hour clock)

   4b. Duration of TUG1: _____ (XX.XX) seconds

   4c. Duration of TUG2: _____ (XX.XX) seconds

   4d. Time to walk 10 meters during usual walking condition: _____ (XX.XX) seconds

   4e. Time to walk 10 meters during Dual task walking condition: _____ (XX.XX) seconds

   4f. Number of subtractions in Dual task condition: _____ (XX)

   4g. Number of mistakes in subtractions: _____ (XX)

   4h. Provide date that data was transferred: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

PPMI Gait Substudy

Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment. Otherwise, complete the "Screen Fail" CRF for this substudy.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria:

1. Enrolled in PPMI Clinical protocol and meets the following criteria based on cohort, as applicable.
    a. Healthy control participants who continue to have no current clinically significant neurological disorder (in the opinion of the Investigator) may enroll at any in-person Clinical visit after Screening
    b. Prodromal participants may enroll at Baseline, Year 1, Year 2, or Year 4 Clinical visit
    c. PD Participants may enroll at Baseline or Year 1 Clinical visit

    ○ Yes ○ No
2. Able to provide informed consent.

    ○ Yes ○ No

Exclusion Criteria:

1. History of stroke or other neurological pathology that causes a change in gait (e.g., Traumatic Brain Injury (TBI), neuropathic pain)

    ○ No ○ Yes

    If yes, prompt information from family.

PPMI Gait Substudy

Screen Fail

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

1. Participant did not enroll in PPMI Gait due to:
   - ○ Eligibility Criteria
   - ○ Participant declined participation prior to completing Baseline visit

   1a. Please select the reason for declining:
   - ○ Risks of Protocol
   - ○ Confidentiality issues
   - ○ Protocol too time intensive
   - ○ Travel requirements
   - ○ Family or caregiver/informant advised declining
   - ○ Physician (other than Site Investigator) advised declining
   - ○ Enrolled in other study
   - ○ No longer interested
   - ○ Other