

PPMI Gait Substudy

ActiGraph LEAP 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 ActiGraph LEAP Activity. 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
ActiGraph LEAP Inclusion/Exclusion Criteria

All inclusion criteria must be marked “Yes” before proceeding to enrollment.

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

Inclusion Criteria:

1. An enrolled prodromal participant in the Gait sub study and has not yet completed the Gait Year 1 visit (first follow up).
 Yes No
2. Willing to provide informed consent for watch activities.
 Yes No

Exclusion Criteria:

(None)

PPMI Gait Substudy
ActiGraph LEAP Assessment

A. Assessment Date: ___ / ___ / _____ (mm/dd/yyyy)

1. Was the ActiGraph LEAP used at this visit?

Yes

No, specify: _____

1a. Indicate the hand the ActiGraph LEAP was worn on:

Right

Left

1b. Indicate serial number of the ActiGraph LEAP:

1c. Provide the date the ActiGraph LEAP was started: ___ / ___ / _____ (mm/dd/yyyy)

PPMI Gait Substudy
ActiGraph LEAP 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either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study.

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 ActiGraph LEAP Activity?
 - No
 - Yes
 - Not Applicable