PPMI Dual PET DPA-714 Imaging Substudy

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 034 Dual PET DPA-714 Imaging 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.

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Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment.

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

Inclusion Criteria:

1. A prodromal PD, PD or Healthy participant enrolled in the PPMI 019 sub study.
   ○ Yes ○ No
2. Able to provide informed consent.
   ○ Yes ○ No

Exclusion Criteria:

1. Any other medical or psychiatric condition or lab abnormality that precludes participation per Investigator's judgement.
   ○ No ○ Yes

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DPA-714 NX PET Imaging

Note: Women of childbearing potential must have a negative urine pregnancy test result prior to injection for imaging scan.

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

1. Was DPA-714 NeuroEXPLORER imaging scan completed?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

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Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a DPA-714 PET imaging procedure to assess for adverse events.

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

1. Was an DPA-714 PET imaging scan 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.

Note: Any adverse events observed should be recorded as related to the parent PPMI 019 substudy.

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Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following a DPA-714 PET imaging procedure to assess for adverse events.

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

1. Was a DPA-714 PET imaging scan conducted at this visit?
   - ○ No
   - ○ Yes

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

   2a. 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: _____

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

If question 3 is "Yes", new adverse event(s) should be documented on the Adverse Event Log.

Note: Any adverse events observed should be recorded as related to the parent PPMI 019 substudy.

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Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following DPA-714 injection, document this in the database within 24 hours of notification.

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

1. This is a report of pregnancy for which person?
   - ○ Female participant
   - ○ Female partner of participant

2. Is the pregnancy confirmed as occurring within 30 days following the DPA-714 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown

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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 or PPMI 019 Substudy.

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 Dual PET DPA-714 Prodromal Imaging Study?
   - ○ No
   - ○ Yes
   - ○ Not Applicable