PPMI Tau Imaging Substudy

Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a PI-2620 PET imaging procedure to assess for adverse events.

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

1. Was a PI-2620 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.

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Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following PI-2620 PET imaging procedure to assess for adverse events.

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

1. Was a PI-2620 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, please 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.

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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 008 Tau 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. Enrolled in PPMI Clinical protocol.

   ○ Yes ○ No

2. Able to provide informed consent.

   ○ Yes ○ No

3. Male or Female (Females must meet additional criteria specified below, further defined in protocol, as applicable)

   a) Females must be of non-childbearing potential or using a highly effective method of birth control 14 days prior to until at least 24 hours after injection of PI-2620.

   b) Females of childbearing potential must not be pregnant, breastfeeding or lactating.

   c) Females of childbearing potential have a negative urine pregnancy test prior to PI-2620 injection on day of PET scan.

   ○ Yes ○ No

Exclusion Criteria:

1. Exposure to an effective radiation dose of 50 mSv, which would be above the acceptable annual limit established by the US Federal Guidelines during the past year.

   ○ No ○ Yes

2. Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.

   ○ No ○ Yes

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PI-2620 PET Imaging

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

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

Vital Signs Measured Approximately 5 - 60 Minutes Prior to Injection

1. Was a study physician present to evaluate the participant prior to injection?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

2. Time vital signs measured prior to injection: __ __:__ __ (24-hour clock)

   To be taken after participant has been supine for 1-3 minutes:

3. Supine blood pressure: _____ / _____ mmHg (systolic/diastolic)
4. Supine heart rate: _____ beats per minute

5. Time of 18F-PI-2620 injection: __ __:__ __ (24-hour clock)

Vital Signs Measured Approximately 15 – 30 Minutes Post-Injection

6. Time vital signs measured after injection: __ __:__ __ (24-hour clock)

   To be taken after participant has been supine for 1-3 minutes:

7. Supine blood pressure: _____ / _____ mmHg (systolic/diastolic)
8. Supine heart rate: _____ beats per minute

9. Was PI-2620 PET imaging scan completed?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

10. Was a study physician (or designee) present to evaluate the participant prior to discharge?

    ○ Yes

    ○ No

    If no, please explain:

    _____

    _____

    _____

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Pregnancy Test

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

B. Is participant of childbearing potential?

○ Yes ○ No

1. If female of childbearing potential, was urine pregnancy test performed?

○ Yes ○ No

1a. If pregnancy test performed, is the participant pregnant?

○ Yes ○ No

1b. Was the pregnancy test result confirmed prior to 18F-PI-2620 injection for PET scan?

○ Yes ○ No ○ Not Applicable

If no, explain why:

_____

_____

_____

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Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following ^{18}F-PI-2620 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 ^{18}F-PI-2620 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown