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.
PPMI Tau Imaging Substudy
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.
PPMI Tau 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 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.
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
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:
      ___________________________________________________________
      ___________________________________________________________
      ___________________________________________________________
PPMI Tau Imaging Substudy

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:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
PPMI Tau Imaging Substudy

Report of Pregnancy

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