PPMI Early Imaging Substudy

Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a dopamine and/or PET imaging procedure to assess for adverse events.

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

1. Was a dopamine or PET imaging scan conducted at this visit?

○ No

○ Yes

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

○ 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 Early Imaging Substudy

Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following a lumbar puncture, skin biopsy, dopamine or PET imaging procedure to assess for adverse events.

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

1. Was an LP, skin biopsy, dopamine or 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.

PPMI Early Imaging Substudy

AV-133 Imaging

Note: Women of childbearing potential must have a negative urine and serum pregnancy test result prior to the baseline imaging scan and must have a negative urine pregnancy test result prior to injection of a follow up imaging scan.

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

Vital signs measured approximately 5 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 [^{18}F]AV-133 injection: __ __:__ __ (24-hour clock)

Vital signs measured approximately 15 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 AV-133 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 Early Imaging Substudy

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 PPMI Early Imaging?
   - ○ No
   - ○ Yes
   - ○ Not Applicable

PPMI Early 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 004 Early 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.

PPMI Early Imaging Substudy

ECG

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

1. Was the electrocardiogram performed? ○ Yes ○ No
2. Time performed: __ __:__ __ (24-hour clock)

Please transcribe the results from the electrocardiogram report cover page

3. Heart rate: _____ beats per minute
4. PR Interval: _____ msec
5. QRS Duration: _____ msec
6. QT Interval: _____ msec
7. QTc: _____ msec

Interpretation

8. Electrocardiogram results are:
   - ○ Normal
   - ○ Abnormal, not clinically significant
   - ○ Abnormal, clinically significant

   If abnormal and clinically significant, please specify the finding from the ECG final report:

   _____

   _____

Any abnormality that is not noted on the Medical Conditions Log at Screening, or has changed in severity from the medical history, should be recorded on the Adverse Event Log.

PPMI Early Imaging 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 "Screen Fail" CRF for this substudy.

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

Inclusion Criteria:

1. A PD participant consented to PPMI Clinical, or a prodromal participant confirmed eligible to proceed to PPMI Clinical Baseline visit.

   ○ Yes ○ No

2. Able to provide informed consent.

   ○ Yes ○ No

3. Women may not be pregnant, lactating or planning pregnancy during the study.

   a. Includes a negative serum pregnancy test prior to Baseline ^{18}F-AV-133 injection.

   b. Includes a negative urine pregnancy test prior to injection of ^{18}F-AV-133 on day of Baseline PET scan.

   c. Women participating in the study must be of *non-childbearing potential* or be using a *highly effective method of birth control* 14 days prior to until at least 24 hours after the last injection of ^{18}F-AV-133.

   ○ Yes ○ No

Exclusion Criteria:

1. Received any of the following medications that might interfere with 18F-AV-133 PET imaging: tetrabenazine (TBZ) or methylphenidate, reserpine, or amphetamine derivative, within 1 month prior to the Screening 18F-AV-133 injection.

   ○ No ○ Yes

2. Have current clinically significant cardiovascular disease or abnormalities on screening ECG (including but not limited to QTc > 450 msec).

   ○ No ○ Yes

3. Are currently taking medications that are known to cause QT prolongation.

   ○ No ○ Yes

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

   ○ No ○ Yes

PPMI Early Imaging Substudy

Pregnancy Test

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

B. Is participant a female of childbearing potential?

○ Yes ○ No

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

   ○ Yes ○ No

   If no, explain why:

   _____

   _____

   _____

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

   ○ Yes ○ No

   1b. Was the pregnancy test result confirmed prior to [^{18}F] AV-133 injection for PET scan?

   ○ Yes ○ No ○ Not Applicable

   If no, explain why:

   _____

   _____

   _____

2. Was serum pregnancy test confirmed negative prior to **Baseline** Visit [^{18}F] AV-133 injection for PET scan?

   ○ Yes ○ No ○ Not Applicable

PPMI Early Imaging Substudy

Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following AV-133 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 AV-133 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown

PPMI Early Imaging Substudy

Screen Fail

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

1. Participant did not enroll in PPMI Early Imaging 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
   - ○ Changed mind about lumbar puncture
   - ○ Travel requirements
   - ○ Family or caregiver/informant advised declining
   - ○ Physician (other than Site Investigator) advised declining
   - ○ Enrolled in other study
   - ○ No longer interested
   - ○ Other