

PPMI Dual PET AV-133 in Prodromal Imaging Substudy
Adverse Event In-Clinic Assessment

Complete this form at a visit that includes an AV-133 PET imaging procedure to assess for adverse events.

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

1. Was an AV-133 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 015 substudy.

PPMI Dual PET AV-133 in Prodromal Imaging Substudy
Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following an AV-133 PET imaging procedure to assess for adverse events.

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

1. Was an AV-133 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 015 substudy.

PPMI Dual PET AV-133 in Prodromal Imaging Substudy
AV-133 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 AV-133 NeuroEXPLORER imaging scan completed?

☐ Yes

☐ No

If no, please explain:

PPMI Dual PET AV-133 in Prodromal 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either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study or PPMI 015 Substudy.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 AV-133 Prodromal Imaging Study?
 - ☐ No
 - ☐ Yes
 - ☐ Not Applicable

PPMI Dual PET AV-133 in Prodromal 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 030 Dual PET AV-133 Prodromal 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 Dual PET AV-133 in Prodromal 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. Prodromal participant enrolled in the PPMI 015 substudy.
☐ Yes ☐ No
2. Able to provide informed consent.
☐ Yes ☐ No

Exclusion Criteria:

1. Any medical or psychiatric condition or lab abnormality that precludes participation per investigator's judgment.
☐ No ☐ Yes

PPMI Dual PET AV-133 in Prodromal Imaging Substudy
Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following [¹⁸F]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 [¹⁸F]AV-133 injection?

- ☐ No
- ☐ Yes
- ☐ Unknown

PPMI Dual PET AV-133 in Prodromal Imaging Substudy
Screen Fail

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

1. Participant did not enroll in PPMI Dual PET AV-133 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