PPMI Dual PET AV-133 in PD 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.

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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.

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AV-133 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 30 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-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 NeuroEXPLORER imaging scan completed?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

10. Was AV-133 Conventional PET imaging scan completed?

    ○ Yes

    ○ No

    If no, please explain:

    _____

    _____

    _____

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

    ○ Yes

    ○ No

    If no, please explain:

    _____

    _____

    _____

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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.

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 PD Imaging Study?
   - ○ No
   - ○ Yes
   - ○ Not Applicable

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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 033 Dual PET AV-133 PD 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 PD 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. Participants over the age of 18 who are enrolled in the PPMI Clinical protocol with a diagnosis of Parkinson's disease (PD) or Healthy Control participants enrolled in the PPMI Clinical protocol.

   ○ Yes ○ No

2. Able to provide informed consent.

   ○ Yes ○ No

3. Male or Female (females must meet additional criteria specified below 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 [^{18}F]AV-133

      - Non-childbearing potential is defined as a female that must be either postmenopausal (no menses for at least 12 months prior to PET scan) or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy).
      - Highly effective method of birth control is defined as practicing at least one of the following: A birth control method that results in a less than 1% per year failure rate when used consistently and correctly, such as oral contraceptives for at least 3 months prior to injection, an intrauterine device (IUD) for at least 2 months prior to injection, or barrier methods, e.g., diaphragm or combination condom and spermicide. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) is not acceptable.

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

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

   ○ Yes ○ No

Exclusion Criteria:

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

   ○ No ○ Yes

2. Any other medical or psychiatric condition or lab abnormality that precludes participation per investigator's judgment.

   ○ No ○ Yes

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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:

_____

_____

_____

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Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following [^{18}F]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 [^{18}F]AV-133 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown

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Screen Fail

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

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