

**PPMI SV2A PET Imaging Substudy**  
**Adverse Event In-Clinic Assessment**

Complete this form at a visit that includes a SV2A PET imaging procedure to assess for adverse events.

A. Assessment Date: \_\_\_ / \_\_\_ / \_\_\_ (mm/dd/yyyy)

1. Was a SV2A 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:

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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 SV2A PET Imaging Substudy**  
**Adverse Event Telephone Assessment**

Complete this form for the telephone follow up 2-3 business days following a SV2A PET imaging procedure to assess for adverse events.

A. Assessment Date: \_\_\_ / \_\_\_ / \_\_\_ (mm/dd/yyyy)

1. Was a SV2A 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 SV2A PET 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either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study.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:

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3. Did increasing PD disability contribute to the decision to withdraw from the PPMI SV2A PET Imaging Study?

- No
- Yes
- Not Applicable

**PPMI SV2A PET 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 014 SV2A PET 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 SV2A PET Imaging Substudy**

**Imaging**

**Note: Women of childbearing potential must have a negative urine pregnancy test result prior to the <sup>18</sup>F-SynVesT-1 injection for PET 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:

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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 <sup>18</sup>F-SynVesT-1 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 SV2A PET imaging scan completed?

Yes

No

If no, please explain:

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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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## PPMI SV2A PET 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 and healthy 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 urine pregnancy test prior to injection of <sup>18</sup>F-SynVesT-1 on day of PET scan.
  - b. 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 <sup>18</sup>F-SynVesT-1. 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

**PPMI SV2A PET 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 prior to <sup>18</sup>F-SynVesT-1 injection for PET scan?

Yes     No     Not Applicable

If no, explain why:

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

Yes     No



## PPMI SV2A PET Imaging Substudy

### Report of Pregnancy

**Note: If a pregnancy was confirmed as occurring within 30 days following  $^{18}\text{F}$ -SynVesT-1 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  $^{18}\text{F}$ -SynVesT-1 injection?

- No
- Yes
- Unknown

**PPMI SV2A PET Imaging Substudy**

**Screen Fail**

A. Assessment Date: \_\_\_ / \_\_\_ / \_\_\_\_\_ (mm/dd/yyyy)

1. Participant did not enroll in PPMI SV2A PET 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