

**PPMI C05-05 PET Imaging Substudy
Adverse Event In-Clinic Assessment**

Complete this form at a visit that includes a C05-05 PET imaging procedure to assess for adverse events.

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

1. Was a C05-05 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 C05-05 PET Imaging Substudy
Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following a C05-05 PET imaging procedure to assess for adverse events.

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

1. Was a C05-05 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 C05-05 PET Imaging Substudy
C05-05 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)

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-C05-05 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 C05-05 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:

11. Imaging Site:

Completed at another PPMI site on behalf of this clinical site

PPMI C05-05 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:

3. Did increasing PD disability contribute to the decision to withdraw from the PPMI C05-05 PET Imaging Study?

- No
- Yes
- Not Applicable

PPMI C05-05 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 021 C05-05 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 C05-05 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. 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 ¹⁸F-C05-05.
 - 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 ¹⁸F-C05-05 injection on day of PET scan. Yes No

Exclusion Criteria:

1. Exposure to a total effective dose equivalent of 50 mSv for the whole body, which is the annual limit established by the US Code of Federal Regulations, 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 C05-05 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?

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 ¹⁸F C05-05 injection for PET scan?

Yes No Not Applicable

If no, explain why:

PPMI C05-05 PET Imaging Substudy
Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following C05-05 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 C05-05 injection?

- No
- Yes
- Unknown

PPMI C05-05 PET Imaging Substudy
Screen Fail

A. Assessment Date: ___ / ___ / _____ (mm/dd/yyyy)

1. Participant did not enroll in PPMI C05-05 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