

PPMI

ADVERSE EVENT LOG

1	3	2
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SUBJECT ID			
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INITIALS		
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SITE NO		
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6	8
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Record all adverse events that occur during the study visit through designated follow-up period following the study procedures listed below. Record disease entity as AE only, if it worsens beyond what investigator expects is within normal range of fluctuation for this subject. Elicit adverse event data by asking an open-ended question, e.g., "What unusual symptoms or medical problems have you experienced since the last visit?" Record any new or change in ongoing sign or symptom as well as any event that has resolved since last evaluation. Enter each change in "severity" on new line. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. IF EVENT IS A SERIOUS ADVERSE EVENT, please refer to the Operations Manual for reporting guidance.

AE # (e.g., 1, 2, etc.)	Adverse Event (Record diagnosis if known)	START DATE (MM/DD/YYYY)	STOP DATE (MM/DD/YYYY)	Severity 1 = mild 2 = moderate 3 = severe	SAE 0 = No 1 = Yes (if Yes, call Coordination Center)	Relationship to Study*	Related to Study Procedure					Check box if this event resulted in withdrawal from the study	Complete when resolved or at Final Visit			
							DATSCAN	LP	AV-133	Skin Biopsy	[18F] Florbetaben		Other	Primary Outcome	AE Status at Final Visit	
						1 = unrelated 2 = unlikely 3 = possible 4 = probable 5 = definite								1 = recovered 2 = under treatment/ observation 3 = change in AE characteristic 4 = sequelae 5 = fatal 6 = unknown	if unresolved, is follow-up required? 0 = No 1 = Yes	

* If 3, 4 or 5 are selected, complete "Related to Study Procedure".

INVESTIGATOR'S SIGNATURE	DATE	STAFF CODE