Patient Initials [ ][ ][ ] PB-SAM Number [ ][ ] [ ][ ][ ]

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PROTOCOL DEVIATION_VIOLATION REPORTING FORM

1.0 Deviation/Violation Details		
1.1	**Date of Event**	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*
1.2	**Type of Event**	☐ **Deviation** ☐ **Violation**
2.0 Deviation/Violation Description		
2.1	**Provide a description of the deviation/violation: State whether the study participants were adversely affected by the deviation/violation; whether the deviation/violation placed the study participants at greater risk; whether the study participants were informed of the deviation/violation and whether the deviation/violation affects the integrity of study data, where applicable.**	

2.2	**Provide an explanation as to why the deviation/violation occurred.**
2.3	**Describe the measures taken to address the deviation/violation.**
2.4	**Describe the measures taken to preclude future recurrence of the deviation/violation.**

2.5	**Subject withdrawn?**	☐ Yes ☐ No
2.6	**Indicate whether the study sponsor has been notified:** *(Sponsor means "CHAIN Coordination Centre "*	☐ Yes ☐ No
2.6.1	**If No, give reason:**	_____ _____
3.0	**CRF Completion**	
3.1	**a) Deviation/violation reported by** *Do not sign if any fields are empty*	__ __ __
	b) Date	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
	c) Time	__ __:__ __ *24 h clock*