

Patient Initials [][][]

PB-SAM Number [1][0][][][]

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	<input type="checkbox"/> Deviation <input type="checkbox"/> Violation

2.0 Deviation/Violation Description

2.1	<p>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.</p>
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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.

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2.5	Subject withdrawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.6	Indicate whether the study sponsor has been notified: <i>(Sponsor means "CHAIN Coordination Centre")</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.6.1	If No, give reason:	<hr/> <hr/>
3.0 CRF Completion		
3.1	a) Deviation/violation reported by <i>Do not sign if any fields are empty</i>	<hr/>
	b) Date	<hr/> <i>DD / MM / YYYY</i>
	c) Time	<hr/> <i>24 h clock</i>