

**Format for Reviewing Protocol Deviation/ Violation  
INSTITUTIONAL ETHICS COMMITTEE  
H M PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD**

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**PROTOCOL DEVIATION/ VIOLATION REVIEW REPORT [Clinical Trial]  
(Please tick the box corresponding to the answer)**

IEC project no.		Date of review:	
Study Title:			
Principal Investigator and Department:			
Type of study:	Investigator initiated:	Pharma:	
	Govt. agency :	Others:	
Date of IEC approval:			
Date of Initiation of the study:			
Duration of study:			
Participant Enrollment No.:		Participant Initials:	
Date of PD/ PV Reporting:			
Describe PD/ PV:			
Explanation for the occurrence:			

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Effect on participant safety:	
Is the participant continuing into the trial:	
Action taken to prevent similar PD/ PV:	
Is the PD/ PV expected to impact the scientific integrity of the study:  If yes, how?	
IEC Recommendation:	

Final Decision at the IEC meeting held on:

**Signature with date**  
**Chairperson, IEC**