

**(Annexure 5)**  
**Protocol Violation/ Deviation Reporting form**  
**(Reporting by case)**  
**Institutional Ethics Committee**  
**Narayana Dental College & Hospital**

**EC Ref. No. (for office use):**

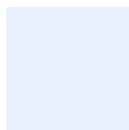
Title of study:  
Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: [Click here to enter a date.](#) Date of start of study: [Click here to enter a date.](#)
2. Participant ID: Date of occurrence: [Click here to enter a date.](#)
3. Total number of deviations /violations reported till date in the study:
4. Deviation/Violation identified by: Principal Investigator/study team  Sponsor/Monitor   
SAE Sub Committee/EC
5. Is the deviation related to (Tick the appropriate box) :

Consenting	<input type="checkbox"/>	Source documentation	<input type="checkbox"/>
Enrollment	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Laboratory assessment	<input type="checkbox"/>	Participant non-compliance	<input type="checkbox"/>
Investigational Product	<input type="checkbox"/>	Others ( <i>specify</i> )	<input type="checkbox"/>
Safety Reporting	<input type="checkbox"/>		
6. Provide details of Deviation/Violation:
7. Corrective action taken by PI/Co-PI:
8. Impact on (if any): Study participant  Quality of data
9. Are any changes to the study/protocol required? Yes  No

If yes, give details

Signature of PI:



[Click here to enter a date.](#)