

The Institutional Ethics Committee

B. J. Medical College & Civil Hospital, Ahmedabad

ANNEXURE 6

Institutional Ethics Committee, B. J. Medical College & Civil Hospital

Assessment report of Serious Adverse Event at the site

Name of the Principal Investigator:	
Protocol No: Protocol Title: _____ _____ _____	
Report Date:	Date of Onset of SAE: _____
<input type="checkbox"/> Initial	<input type="checkbox"/> Follow-up
No. of Follow-up <input type="checkbox"/>	
Attach a narrative for details of SAE, history of the case and relevant laboratory findings and treatment given:	
Outcome of SAE: <input type="checkbox"/> resolved <input type="checkbox"/> on-going	
Seriousness: <input type="checkbox"/> Death <input type="checkbox"/> Life threatening <input type="checkbox"/> Hospitalization <input type="radio"/> initial <input type="radio"/> prolonged <input type="checkbox"/> Disability / Incapacity <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Any Other... _____	Relation to <input type="radio"/> Drug <input type="radio"/> Device <input type="radio"/> study procedure <input type="checkbox"/> Not related <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Definitely related <input type="checkbox"/> Unknown
Signature of the Principal Investigator:	
Date:	

IEC Comments:

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B. J. Medical College & Civil Hospital, Ahmedabad

Signature of Chairperson and Member Secretary with date:

Action taken by the Chairperson:

- To be discussed in Emergency meeting of IEC
- To be discussed in next scheduled IEC meeting
- To be sent to independent consultant(s) / subject expert opinion

Name of the expert/s _____

- Any other _____

Decision at the IEC meeting held on _____

- Noted and follow up report requested(if applicable) No Yes

- Changes to the protocol recommended? No Yes

Recommendations:

- Changes to the informed consent form recommended? No Yes

Recommendations:

- Request for additional information

Additional Information needed:

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Till additional information is received,

- New recruitment withheld the study
- Terminate the project

Reasons for termination:

- Any other

Signature with Date

Chairperson