

**Format of IEC Report to CDSCO in case of SAE
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD**

To,

Assistant Drug Controller [I]
Central Drugs Standard Control Organization [CDSCO]
Office of Drug Controller General (India)
FDA Bhawan, Kotla Road, New Delhi 110002
Date:

Reference: Protocol Number:
 Centre Number:

Subject: Opinion on Serious Adverse event (SAE) Death/ Injury other than death
 Patient ID:

Dear Sir,

Details of examination of the said SAE [including key events]

Minutes of the meeting

Ethics Committee Analysis

Causality assessment and justification

- WHO Causality Categories/ Naranjo Tool criteria
- Criteria under Rule 122DAB and Appendix XII of Schedule Y of Drugs and Cosmetics Rules' [criteria from 'a' to 'g' under the said rules]

Opinion [report]

Member Secretary, Institutional Ethics Committee,
HM Patel Centre for Medical Care and Education
Karamsad, Gujarat – 388325