

Format for Site Monitoring Report
INSTITUTIONAL ETHICS COMMITTEE
H M PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD

SITE MONITORING VISIT REPORT [Clinical Trial]

IEC Project no.:	Date of the visit :
Study title:	
Principal Investigator:	
Department:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs including reasons:
Are the present study team members as per the list approved by the IEC:	Comment:
Are site facilities appropriate?	Comment:
Is recent version of informed Consent Document (ICD) used?	Comment:
Is it approved by the IEC?	Comment:
Whether consent has been taken from all participants/ LAR?	Comment:
Whether appropriate vernacular consent has been used?	Comment :
Any other findings noted about the ICDs:	Comment:
Is recent version of protocol used?	Comment:
Is it approved by the IEC?	Comment:
Any adverse events found?	Comment:

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Any SAEs found?	Comment:
Were the SAEs informed to HREC within 24 hours?	Comment:
Any there any protocol non-compliance/ deviations/ violation?	Comment:
Have the protocol non –compliance deviation/ violation been informed to IEC?	Comment:
Are all Case Record forms up to date?	Comment:
Are storage of data and investigating products locked?	Comment:
How well are participants protected?	Comment:
Any outstanding tasks or result of visit?	Comment:
Duration of visit: hours	Starting from: Finish:
Name of IEC members and representatives who attended the monitoring visit:	
Signature:	

Signature with date
Chairperson, IEC