

Format for Site Monitoring Report
INSTITUTIONAL ETHICS COMMITTEE - 2
H M PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD

SITE MONITORING VISIT REPORT [Non-regulated project]

	Date of the visit :
Study title:	
Principal Investigator:	
Total number of participants enrolled:	Total participants ongoing:
Are the present study team members as per the list approved by the IEC:	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? [sample form to be examined]	Comment:
Whether appropriate vernacular consent has been used? [sample form to be examined]	Comment:
Any other findings noted about the ICDs:	Comment:
Any there any protocol non-compliance/ deviations/ violation?	Yes/ No If yes, whether informed to IEC: Yes/ No
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 member[s] who attended the monitoring visit:	
Signature:	

Signature with date
Chairperson, IEC