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

SITE MONITORING VISIT REPORT [Clinical Trial]

(Please tick the box corresponding to the answer)

<table>
<tr><td colspan="2">IEC project no.</td><td colspan="2">Date of Visit:</td></tr>
<tr><td colspan="4">Study Title:</td></tr>
<tr><td colspan="4">Principal Investigator and Department:</td></tr>
<tr><td rowspan="2">Type of study:</td><td>Investigator initiated:</td><td colspan="2">Pharma:</td></tr>
<tr><td>Govt. agency :</td><td colspan="2">Others:</td></tr>
<tr><td colspan="4">Date of IEC approval:

Date of Initiation of the study:

Duration of study:</td></tr>
<tr><td rowspan="5">Reason for monitoring:</td><td rowspan="5">Routine:</td><td colspan="2">For cause (State reason/s)</td></tr>
<tr><td colspan="2">Protocol violations/Deviations</td></tr>
<tr><td colspan="2">SAE reporting</td></tr>
<tr><td colspan="2">Recruitment rate</td></tr>
<tr><td colspan="2">Others</td></tr>
<tr><td>Last monitoring done, if any,</td><td>Yes

Date of last monitoring</td><td colspan="2">No</td></tr>
<tr><td colspan="4">Project Status:
1. Ongoing
2. Completed
3. Recruitment Completed
4. Follow-up, extension study
5. Suspended
6. Terminated
In case of the response to the above question is option 5 or 6, kindly provide reason/s:</td></tr>
</table>

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Recruitment Status: Total participants to be recruited: Screened: Screen Failures: Enrolled: Withdrawn: Reason: Discontinued: Reason: Completed: Active:	
Are the present study team members as per the list approved by the IEC? Yes/ No	Comment:
Are site facilities appropriate? Yes/ No	Comment:
Is intimation and approval from participant noted in the source document with regards to current risk benefit information? Yes/ No	Comment:
Is the recent version of Informed Consent Document (ICD), after IEC approval, used? Yes/ No	Comment:
Whether appropriate vernacular consent has been taken from all patients? Yes/ No	Comment:
Any other findings noted about the ICDs? Yes/ No	Comment:
Is recent IEC approved version of protocol used? Yes/ No	Comment:
Any deviation from recruitment strategy declared at the time of approval? Yes/ No	Comment:
Has the eligibility, inclusion exclusion criteria been adhered to? Yes/ No	Comment:
Any adverse events found?	Comment:

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Yes/ No	
Any SAEs found? Yes/ No	Comment:
Were the SAEs informed to IEC within timelines specified by CDSCO? Yes/ No	Comment:
No. of deaths reported: -Death unrelated to the participation in trial: - Death possibly related to the participation in trial: - Death related to the participation in trial: Any other non-death study related injury	---------- _____ _____ Yes/ No/ NA Comments (If Any) _____ _____
Compensation paid for study related injury or death Yes/ No/ NA	Comments (If Any)
Is there any protocol non-compliance? deviations/violations? Yes/ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC? Yes/ No	Comment:
Are all Case Record Forms up to date? Yes/ No	Comment:
Are storage of data and investigating products locked? Yes/ No	Comment:
How well are the participants protected? Good/ Fair/ Not good	Comment:
Any other remarks	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of IEC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on:

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Signature with date
Chairperson/ MS, IEC