

# Ethics Committee for Research on Human Subjects

## Seth GS Medical College & KEM Hospital



Established in 1986

Recognized by: The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP) for its compliance with international and local standards in ethical review

**Dr. M. L. Kothari**  
Chairperson

**Dr. Sunil Kuyare**  
Member Secretary

### Annexure 1

AX 01/SOP 11/V3.1

#### Study Completion Report Form

(Filled by Principal Investigator)

ECRHS Protocol No:	
Protocol Title: _____ _____ _____ _____ _____	
Principal Investigator:	
Department:	
Total no. of study participants recruited	
Total no. of study participants approved by the ECRHS for recruitment	
Duration of the study	
*Results (Summary) with Conclusion: (use extra blank paper, if more space is required). _____ _____ _____	
*Note: If the final report is not available from sponsor, it may be submitted later to the ECRHS once it is ready.	
Number of SAEs at our center:	
Whether all SAEs intimated to the ECRHS	Yes <input type="checkbox"/> No <input type="checkbox"/>
No. of patients withdrawn and reasons for withdrawal:	<input type="checkbox"/> _____ _____ _____ _____
Signature of Principal Investigator	Date :-

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### Assessment by the ECRHS member

#### To be reviewed by

- Chairperson / Member Secretary only and informed to the ECRHS members at Full Board ☐
- Full Board ☐
- Any 2 ECRHS members and informed to the ECRHS members at Full Board ☐

Names of ECRHS members:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signature with date: \_\_\_\_\_

Chairperson

Reviewer's Name: \_\_\_\_\_

Comments(if any)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### Action taken:

- ☐ Noted
- ☐ Requires more information/ action as follows:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature with date : \_\_\_\_\_  
of the Reviewer

Final Decision by the Chairperson

\_\_\_\_\_  
\_\_\_\_\_

Signature with date: \_\_\_\_\_

Chairperson