

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 5 AX 05/SOP 05-A/V 7 Delegation of Responsibilities of Study Team

Date:

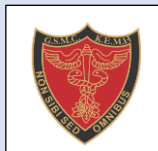
IEC No. of the Project:

Study Title:

.....

Name	Role	No.
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6
	Study co-ordinator *	7
	Study co-ordinator *	7
	Laboratory Technician	8
	Any Other Role	9
		10

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor) (Please place tick marks against assigned duties for each member in the following table)



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Code	TASKS	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7	Role 8	Role 9	Role 10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug, document drug dispensing, storage & accountability										
O	Person to whom research participants should										



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	contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Signature with date of Principal Investigator: