



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 5 AX 05/SOP 05-A/V 7.1 Delegation of Responsibilities of Study Team

Date:

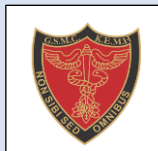
IEC No. of the Project:

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)



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

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										



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

	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: