

Annexure 5 AX 05/SOP 05/V6.1



Delegation of Responsibilities of Study team INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Date: _____

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
		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)

Code	TASKS	Role									
		1	2	3	4	5	6	7	8	9	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 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: _____