

12	Dr. Amita Maheshwari Member	Professor, Dept. of Surgery, Tata Memorial Hospital, TMC.	Female	Clinician (Surgical oncology)
13	Dr. Tanuja Teni Member	Principal Investigator, Scientific Officer 'G', ACTREC	Female	Basic Scientist
14	Dr. Shilpee Dutt Member	Principal Investigator, Scientific Officer, ACTREC	Female	Basic Scientist
15	Dr. P.G. Subramanian Member	Professor, Pathologist 'F', Officer in-charge Hematopathology Lab, ACTREC, TMC	Male	Basic Medical Scientist

The following documents were reviewed:

1. Covering letter dated 24.07.2018
2. 1st Year Budget Sheet
3. Project Submission Form
4. Study Protocol version 1 dated 13.07.2018
5. ICFs in English, Hindi and Marathi Version 1 dated 13.07.2018
6. CV and GCP of PI and CO-PI and Co-I
7. Reply to IEC query letter dated 06.09.2018
8. Revised submission template
9. Summary of changes
10. AML Study Protocol Version 1.1 dated 05.09.2018 (Approved)
11. ICF in English, Hindi and Marathi Version 1.1 dated 05.09.2018 (Approved)

Recommendation to PI:

- The study should be initiated only after registration of the study with Clinical Trials Registry India (CTRI). PI is requested to submit Final CTRI reg. no before the enrollment of first participant.

Decision: Approved. IEC approved the study till 01.10.2021. It is mandatory to submit study status report annually. Failure to submit the annual status report may result in withdrawal of IEC approval. You are requested to submit annual status report on or before 01.10.2019.

Your request for Intra Mural funding support will be forwarded to TRAC for further action.

Following points must be noted:

1. IEC has approved recruitment 150 subjects on this study.
2. IEC should be informed of the yearly progress of the study by the PI. In order to ensure that there is no lapse in the IEC approval period, it is mandatory to submit study status report 3 months (90 days) prior to lapse of study validity.
3. IEC has approved the conduct of the study at TMC (TMH and ACTREC).
4. Principal Investigator and study team should be GCP trained.
5. PI and other investigators should notify initiation of the study. Principal Investigator should intimate the IEC after accrual of first 10 participants in the study or after 6 months of initiation of study whichever is earlier.
6. PI and other investigators should co-operate fully with data and safety monitoring Sub-committee (DSMSC), who will monitor the study from time to time.