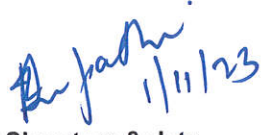
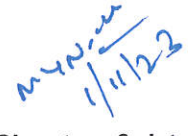
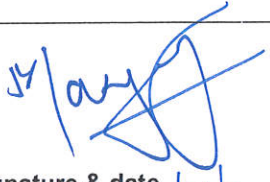

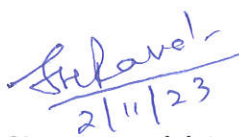


SOP Addendum 4 dated 1st November 2023
Effective from 5th November 2023 to SOPs version 6.1

1. In regard to clinical research studies/ trials (regulatory trials and academic clinical trials), if an IEC approved affiliated study team member leaves the institute (anybody who resigns from KEMH, is transferred out of KEMH, or is affiliated to KEMH in some way but not on regular biometric attendance system or death of the study team member) he/she ceases to be part of the trial.
2. It is the responsibility of the Principal Investigator (PI) to ensure that the said person is removed from duty delegation log with immediate effect. This is to be informed to the sponsor (if applicable) and IEC. IEC will review and accord approval for the revised duty delegation. The last working day would be the end date in the duty delegation log.
3. All PIs should make appropriate changes in departmental clinical research SOPs pertaining to the above matter.

Prepared by	Dr. Raakhi Tripathi, Member Secretary, IEC-I	 Signature & date 1/11/23
Reviewed by	Dr. Milind Nadkar, Member, IEC-I	 Signature & date 1/11/23
Approved by	Dr. Manju Sengar, Chairperson, IEC-I	 Signature & date 2/11/2023
Accepted by	IEC-I	
 Signature and date 2/11/23 Dr. Sangeeta Ravat, Dean, Seth GSMC and KEMH		

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