Department of Clinical Pharmacology,
Seth G.S. Medical College & KEM Hospital, Parel, Mumbai: 400012

Index of Standard Operating Procedures (SOPs)

Sr. No.	Title of the SOP	Status	Revision Due Date
Ph. 1 SOP 00	Preparing a Standard Operating Procedure(SOP)	Effective	31/Dec/2025
Ph.1 SOP 00a	Amending a Standard Operating Procedure(SOP)	Effective	31/Dec/2025
DCP/Ph1/001	Procedure for collection of blood samples of trial participants	Effective	31/Dec/2025
DCP/Ph1/002	Waste Management	Effective	31/Dec/2025
DCP/Ph1/003	Procedure to use and Maintain Infusion pump	Effective	31/Dec/2025
DCP/Ph1/004	Procedure to use Multipara monitor	Effective	31/Dec/2025
DCP/Ph1/005	Procedure to use ECG machine	Effective	31/Dec/2025
DCP/Ph1/006	Procedure to use defibrillator	Effective	31/Dec/2025
DCP/Ph1/007	Procedure for transfer of patients to gastrointestinal surgery ICU (Liver ICU) including the use of transport ventilator in case of emergency	Effective	31/Dec/2025
DCP/Ph1/008	Review and updation of Emergency Tray/Crash Cart	Effective	31/Dec/2025
DCP/Ph1/009	Protocol for emergency evacuation in the event of fire	Effective	31/Dec/2025
DCP/Ph1/010	Measurement of Blood Pressure using a sphygmomanometer	Effective	31/Dec/2025
DCP/Ph1/011	Identification (and advertisement) for potential subjects for a Phase I trial with an investigational product (IP) – both healthy participants and patient participants	Effective	31/Dec/2025
DCP/Ph1/012	Obtaining written informed consent from potential participants taking part in clinical trials	Effective	31/Dec/2025

DCP/Ph1/013	Screening of potential participants for a Phase I clinical trial with an Investigational Product (IP)	Effective	31/Dec/2025
DCP/Ph1/014	Collection and review of screening data for selection of participants for a Phase I clinical trial with an Investigational product	Effective	31/Dec/2025
DCP/Ph1/015	Standard Operating Procedure (SOP) for Managing and Recording Data Related to Screen Failures and Participants Who Withdrew Consent	Effective	31/Dec/2025
DCP/Ph1/016	Managing a pharmacy for storage of investigational products for clinical trials	Effective	31/Dec/2025
DCP/Ph1/017	Management of investigational products for a Phase I clinical trial	Effective	31/Dec/2025
DCP/Ph1/018	Dispensing of Investigational Products for a Phase I clinical trial	Effective	31/Dec/2025
DCP/Ph1/019	Evaluation of readiness of a Phase I clinical trial facility for conduct of a study in participants	Effective	31/Dec/2025
DCP/Ph1/020	Preparation of trial master file for clinical trials	Effective	31 /Dec/2025
DCP/Ph1/021	Training of investigators / co-investigators, scientist(s), pharmacist(s), nurses, technicians and other trial staff for a Phase I clinical trial with an Investigational product.	Effective	31/Dec/2025
DCP/Ph1/022	Training Members of Data Safety Monitoring Board (DSMB) for a Phase 1 Clinical Trial with an Investigational Product	Effective	31/Dec/2025
Ph.1 SOP A05	Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages	Effective	31/Dec/2025
Ph.1 SOP A09	Managing initial submission of protocol and associated documents for approval by Institutional Ethics Committee	Effective	31/Dec/2025