Standard Operating Procedures

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

Sr. No.	Title of the SOP	Status	Revision Due Date
D 01/05	Preparing Standard Operating Procedures (SOPs) for clinical trial related activities in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai	Effective	31/Dec/2023
D 02A/05	Preparing the site team for a clinical study sponsored by a pharmaceutical company	Effective	31/Dec/2023
D 02B/05	Preparing the site team for an Investigator initiated clinical study	Effective	31/Dec/2023
D 03/05	Responsibilities of the study team	Effective	31/Dec/2023
D 04/05	Obtaining approval from the Institutional Ethics Committees	Effective	31/Dec/2023
D 05/05	Administering and documenting written informed consent	Effective	31/Dec/2023
D 06/05	Screening participants for participation in any clinical study	Effective	31/Dec/2023
D 07/05	Recruitment of research participants	Effective	31/Dec/2023
D 08/05	Birth Control measures for male participants	Effective	31/Dec/2023
D 09/05	Birth Control measures for female participants	Effective	31/Dec/2023
D 10/05	Procedure for collection of blood samples of trial participants	Effective	31/Dec/2023
D 11/05	Dispensing Investigational Product (IP)	Effective	31/Dec/2023
D 12/05	Source Documentation	Effective	31/Dec/2023
D 13/05	Dealing with protocol deviations and violations in any clinical study	Effective	31/Dec/2023
D 14/05	Adverse Event (AE) Monitoring, Recording and Reporting	Effective	31/Dec/2023

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D 15/05	Serious Adverse Event (SAE) Monitoring, Recording and Reporting	Effective	31/Dec/2023
D 16/05	Establishing a Trial Master File (TMF)	Effective	31/Dec/2023
D 17/05	Continued interaction with the Institutional Ethics Committees	Effective	31/Dec/2023
D 18/05	Archiving	Effective	31/Dec/2023
D 19/05	Preparing for Monitoring	Effective	31/Dec/2023
D 20/05	Receipt, Inventory and storage of Investigational Product (IP)	Effective	31/Dec/2023
D 21/05	Contact and communication with sponsor	Effective	31/Dec/2023
D 22/05	Storage of Investigational product (IP) and Maintaining its Temperature Log	Effective	31/Dec/2023
D 23/05	Destruction/Return of Investigational product	Effective	31/Dec/2023
D 24/05	Waste Management	Effective	31/Dec/2023
D 25/05	Separation, Storage and Shipment of Blood Samples	Effective	31/Dec/2023
D 26/05	Standard Operating Procedure for Internal Monitoring	Effective	31/Dec/2023
D 27/05	Audio Visual (AV) recording of informed consent process	Effective	31/Dec/2023
D 28/05	Ensuring continuity of trial in case of staff and investigator attrition	Effective	31/Dec/2023
D 29/05	Remote Monitoring	Effective	31/Dec/2023