



SOMANI HOSPITAL

277-278, Shri Gopal Nagar, 80 Ft. Road Gopalpura Bypass, Jaipur-302019
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SOMANI HOSPITAL

STANDARD OPERATING PROCEDURE FOR

CLINICAL TRIAL DEPARTMENT

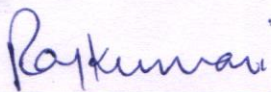
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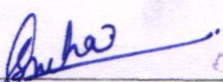
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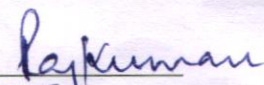
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Administrative head

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Date


01/Aug/2025

Site SOP_Somani Hospital_Version No. 2.3, dated 01-Aug-2025



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I. ABBREVIATIONS

ADR- Adverse Drug Reaction

AE- Adverse Event

BA/BE- Bioavailability/ Bioequivalence

PI-Principal Investigator

IP-Investigational Product

IB- Investigator Brochure

CRF- Case Report Form

FDA- Food and Drug Administration

GCP-Good Clinical Practice

ICF- Informed Consent Form

ICH-International Conference on Harmonization

LAR- Legally Acceptable Representative

SAE-Serious Adverse Event

SC-Study Coordinator

SIV- Site Initiation Visit

SOP- Standard Operating Procedure

DCGI- Drug Controller General of India

DSMB-Data Safety Monitoring Board

GMP- Good Manufacturing Practice

NDA- New Drug Application

RCT- Randomized Controlled Trial

ICMR-Indian Council of Medical Research

IND- Investigational New Product

IRB- Institutional Review Board

CTA-Clinical Trial Agreement

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II. REFERENCES

Clinical Trials Rules dated 19th March 2019

ICH Harmonized Tripartite guideline GCP, dated 10 June 1996

GOOD Clinical Practices (GCP) Guidelines issued by the Central Drugs Standard Control Organization.

Directorate general of health services, Government of India

Ethical guidelines for biomedical research on human participants by ICMR, New Delhi.

Drug and Cosmetic Act (3rd amendment 8 Feb 2013)

Drug and Cosmetic (IInd amendment) Rules, 2016

Gazette Notification G.F.R. 11(E) dated 6th Jan, 2016

Gazette Notification G.F.R. 611(E) dated 31st July, 2015

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