



Somani Hospital Ethics Committee

Somani Hospital Ethics Committee,

Jaipur, Rajasthan, India

Standard Operating Procedure (SOP)

Version 1.6 dated 31-MAY-2025_EC SOP

EC Registration No.: ECR/1531/Inst/RJ/2021 issued date 06-Apr-2021

SOP NUMBER: SHEC/SOP-01	VERSION NUMBER: 1.6
EFFECTIVE DATE: 31-MAY-2025	VALIDITY DATE: 30-MAY-2028
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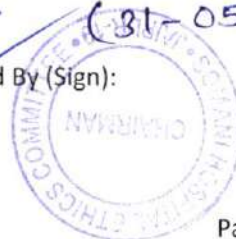
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APPROVED BY:	
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Signature:	Date: 31-MAY-2025

Reviewed By (Sign): (31-05-2025)



Approved By (Sign): (31-05-2025)



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Address

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Somani Hospital Ethics Committee

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I. ABBREVIATIONS

ADR-	Adverse Drug Reaction
AE-	Adverse Event
CFR-	Code for Federal Regulation
CIOMS-	Council for International Organizations of Medical Sciences
CRF-	Case Report Form
CTA-	Clinical Trial Agreement
DCGI-	Drug Controller General of India
DSMB-	Data Safety Monitoring Board
FDC-	Fixed Dose Combination
GCP-	Good Clinical Practice
GMP-	Good Manufacturing Practice
IB-	Investigator Brochure
ICF-	Informed Consent Form
ICH-	International Conference on Harmonization
ICMR-	Indian Council of Medical Research
IND-	Investigational New Product
IP-	Investigational Product
IRB-	Institutional Review Board
LAR-	Legally Acceptable Representative
NDA-	New Drug Application
PI-	Principal Investigator
RCT-	Randomized Controlled Trial
SAE-	Serious Adverse Event
SIV-	Site Initiation Visit
SOP-	Standard Operating Procedure
SHEC-	Somani Hospital Ethics Committee

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II. REFERENCES

- New Drugs and Clinical Trials Rules 2019
- ICH Harmonized Tripartite guideline GCP, dated 10 June 1996
- E6(R2) GCP guidelines: addendum to ICH E6(R1) dated March 2018
- 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.S.R. 889(E) dated 12th Dec, 2014
- Gazette Notification G.S.R. 611(E) dated 31st July, 2015
- Gazette Notification G.S.R. 69(E) dated 03rd Feb, 2015
- Gazette Notification G.S.R. 11(E) dated 6th Jan, 2016
- Gazette Notification G.S.R. 287(E) dated 08th Mar, 2016

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