



TATA MEDICALCENTER

**Tata Medical Center
Institutional Review Board**

SOP: TMC/IRB/SOP-13

Version No.: 13.1

Effective Date:

03-10-2025

To be reviewed (on or before):

31-03-2026

TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission

Checklist for EC form:

DOCUMENTS	RESPONSE		
	YES	NO	NA
Submission Letter	✓		
Complete Submission Dossiers	✓		
Summary of Protocol	✓		
Undertaking by Investigator	✓		
Patient Information Sheet	✓		
Case Record Form	✓		
Updated CV, GCP and MRC of PI and all the respective Co-I's	✓		
Completed SOP 4	✓		
Draft CTA (if available)	✓		
RSD Approval	✓		
Study Budget (detailed budget sheet)	✓		
IBSC Checklist (for projects handling with micro- organisms)	✓		
CTRI Registration Sheet	✗	✓	
CDSCO Submission	✓		
DCGI Approval		✓	
Study Presentation (min 5 slides; max 7 slides)	✓		