



TATA MEDICAL CENTER

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

# TMC/ IRB/ SOP-4

## Standard Operating Procedure (SOP)

For,

## Initial Study Submission

**Annexures**

Prepared by : Dr Indranil Mallick

IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder

TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun

Head of the Institution





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**Annexure 1: INITIAL STUDY SUBMISSION FORM**


Section A: Title and Principal Investigator		
Study title	Assessment of fall risk and its contributing factors in patients and evaluate the practice adherence to fall prevention SOP among staff nurses in a selected hospital of Kolkata	
	<b>Name</b>	<b>Affiliation</b>
Principal Investigator	Prof. Dr. Piyali Bose	Chief Nursing Superintendent cum Professor
Co-Principal Investigator	Dakshina Singh Lohar	M.Sc Nursing 1st year
Co-Principal Investigator		
Section B: Type of Study		
By Origin	<input type="checkbox"/> Industry Sponsored <input checked="" type="checkbox"/> Investigator Initiated	
Sponsor Details		
By Design	<input checked="" type="checkbox"/> Observational <input type="checkbox"/> Interventional	
For Interventional studies only		
Phase of Study	<input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Bioavailability/ Bioequivalence (BA/ BE) study <input type="checkbox"/> Pre- Clinical Study <input checked="" type="checkbox"/> None of the Above (please specify intervention below)	
Type of intervention Please select all the interventions applicable. The intervention may be an addition to or a modification of the current standard of care	<input type="checkbox"/> Drug <input type="checkbox"/> Vaccine <input type="checkbox"/> Device <input type="checkbox"/> Radiotherapy <input type="checkbox"/> Radioisotope <input type="checkbox"/> Surgery <input type="checkbox"/> Diagnostic test <input type="checkbox"/> Supportive Therapy <input checked="" type="checkbox"/> Educational Intervention <input type="checkbox"/> Other	
Is this a regulatory trial? Regulatory trials will require DCGI permission before IRB approval. Evidence of permission or DCGI application with the current status of application has to be notified at the time of submission for review of proposal.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Is this an investigational new drug (IND) or first in human drug study?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

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<b>Section C: Centers and Participants</b>		
<b>Enrolling Centers</b>	<input checked="" type="checkbox"/> Single Center <input type="checkbox"/> Multicenter	
(for multicenter studies) <b>Number of participating centers</b>		
<b>International enrolment</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>Total planned sample size</b>		
<b>Estimated/ Planned enrolment at Tata Medical Center</b>		
<b>Will vulnerable subjects be enrolled</b>	<div style="text-align: center;"> <input type="checkbox"/> Yes      <input type="checkbox"/> No  <i>(If Yes, Please Indicate)</i> </div> <div style="margin-top: 10px;"> <input type="checkbox"/> Children;    <input checked="" type="checkbox"/> Employees of the Institute  <input checked="" type="checkbox"/> Patients, who are in Critical Care  <input type="checkbox"/> Economically/ Socially Backward  <input type="checkbox"/> Unable to understand written documentation  <input type="checkbox"/> Others         </div>	
<b>Informed Consent</b> All consent forms must be submitted in English, Bengali and Hindi with valid translation and back-translation certificates before IRB review.	<input type="checkbox"/> Consent Waiver Requested <input checked="" type="checkbox"/> Standard Informed Consent form for Adult Subject <input type="checkbox"/> Informed consent form for legally authorized representative (for all children and those adults incapable of consenting) <input type="checkbox"/> Assent form (applicable for children between 7-15 in addition to informed consent for LAR)	
If consent or assent form is to be used, it includes all the recommended components as advised in the ICMR Ethical Guidelines 2017. <a href="https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx">https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx</a>	<input checked="" type="checkbox"/> Yes, I Confirm...	
<b>Does your study have a Data and Safety Monitoring Committee (DSMC)?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

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Section D: Funding, Insurance and Indemnity	
Total budget of the study (in INR)	INR 200000/-
Who will fund the following	
Trial Intervention	<input type="checkbox"/> Subject <input type="checkbox"/> Industry Sponsor <input type="checkbox"/> Institute as Sponsor <input checked="" type="checkbox"/> NA
Cost of Serious Adverse Events	<input type="checkbox"/> Subject <input type="checkbox"/> Industry Sponsor <input type="checkbox"/> Institute as Sponsor <input checked="" type="checkbox"/> NA Sponsor may avail of Clinical Trial Insurance
Compensation for Trial Related Injury	<input type="checkbox"/> Subject <input type="checkbox"/> Industry Sponsor <input type="checkbox"/> Institute as Sponsor <input checked="" type="checkbox"/> NA Sponsor may avail of Clinical Trial Insurance
If the answer to any of the above questions is 'Subject', please explain below:	
<b>Does your trial have clinical trial indemnity for investigators?</b> All sponsored interventional studies must provide documentation of indemnity for trial investigators and staff. All investigator-initiated interventional studies should have trial indemnity, please contact the IRB office for details.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Does the sponsor of the trial have clinical trial insurance?</b> All sponsored interventional studies must provide documentation of trial insurance. All investigator-initiated interventional studies of new treatments that are currently not standard of care and likely to result in SAEs in the interventional arm should consider trial insurance for cost of serious adverse events. Contact the IRB office for details.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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<b>Section E: Special Considerations</b>	
<b>Does the project involve bio-banking any blood or tissue?</b> If bio-banking is planned at Tata Medical Center, please provide documentation that confirms that the TMC bio-bank and you are mutually aware of the requirements and SOPs.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Does your project involve the use of stem cells?</b> If yes, please make sure you are aware of the DBT-ICMR guidelines for Stem Cell Research. <a href="https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf">https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf</a>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Does your project involve the use of infectious material?</b> If yes, please provide clearance from the Institutional Biosafety Committee (IBSC)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Does your project involve the use of radioactive isotopes?</b> If yes, please provide clearance from the appropriate governmental agencies.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Does your project involve the development or use of artificial intelligence tools?</b> If yes, please make sure you are aware of the ICMR guidelines for the application of Artificial intelligence in Biomedical Research and Healthcare. <a href="https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare">https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare</a>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Section F: Collaboration or sharing data/materials with external institutions or agencies</b>	
<b>Does your project involve sharing of data, digital samples (images/sequencing data etc.) or biological samples of any form with any external institution/agency?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, I confirm that there is a <b>data/ material transfer agreement</b> in consideration between the institution and external agency covering all of the following	Privacy Preservations Rights of access and use Safekeeping and archiving Disposal of digital and/ or biological material
<b>Does your project involve funding or collaboration with any foreign agency or institution?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>If yes, do you have clearance from the Health Ministry Screening Committee (HMSC)?</b> Please check the following for details: <a href="https://main.icmr.nic.in/content/health-ministry-screening-committee-hmsc">https://main.icmr.nic.in/content/health-ministry-screening-committee-hmsc</a>	<input type="checkbox"/> Yes <input type="checkbox"/> In Progress





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**Signatures**

By signing the document, I acknowledge that I am aware of the details of the research protocol and that all the answers to the questions above are true to the best of my knowledge.

	Name	Signature	Phone number & E-mail
<b>Principal Investigator</b>	Prof. Dr. Piyali Bose	<i>Piyali Bose</i>	9433888242 piyali.bose@gmail.com
Co-PI Co-I	Dakshina Singh Lohar	<i>Dakshina Singh Lohar</i>	6296575157 daxu.005@gmail.com
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			

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**Statement of Compliance:**

We, hereby, declare that, the information given above is true and that we will comply with the guidelines mentioned in the NDCT (Third Amendment) Rules, 2022 (Drugs and Cosmetic Act 1940), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2001) and the International Conference on Harmonization Good Clinical Practices (ICH GCP) Guidelines (1996) while conducting the research study.

**Name and Signatures of Principal Investigator with Date**

Name	Signature	Date
Prof. Dr. Piyali Bose	Piyali Bose	4/4/26

**Name and Signatures of Co-Investigator(s) with Date**

Name	Signature	Date
Dakshina Singh Lohar	Dakshina Singh Lohar.	04/04/26

**Name and Signatures of Head of Department(s) with Date**

Name	Signature	Date
Prof. Dr. Piyali Bose	Piyali Bose	7/7/26
Chitra Sengupta	esengupta	4.4.26

Stamp/ Seal of the Department(s)

Prof (Dr) Piyali Bose  
PhD in Nursing, M. Sc Pediatric Nursing  
Chief Nursing Superintendent  
Tata Medical Center, Kolkata

Prof. Chitra Sengupta  
Principal  
Tata Medical Center  
Kolkata

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### **Annexure 3: Check List of Documents for Protocol Submission (by the study team)**

S/N	Document	Yes	No	Date/ If pending	NA
1)	Project submission application duly filled	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
2)	Letter to Member Secretary/Chairperson	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
3)	Summary of protocol (in not more than 500 words)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
4)	Protocol	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
5)	Amendments to protocol	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
6)	Informed consent document in English	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
7)	Informed consent document in Regional languages (Total No. : 2 )	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
8)	Back translations of Informed consent documents	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
9)	Translation and Back translation certificates of Informed consent documents	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
10)	Amendments to the Informed consent documents	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
11)	Case Record Form	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
12)	Subject recruitment procedures : advertisements, notices	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
13)	Patient instruction card, identity card, diary etc.	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
14)	Patient/subject questionnaire(s) (No.:____)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
15)	Insurance policy (only one copy is needed for submission)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
16)	Investigator's undertaking to DCG(I) (one copy)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
17)	DCG(I) approval (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
18)	Investigator's agreement with sponsor (copy of final signed document)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
19)	DCG(I) marketing/manufacturing licence for herbal formulations/nutraceuticals (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
20)	Health Ministry Screening Committee (HMSC) approval, in case the study involves collaboration with any foreign laboratory/clinic/institution (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
21)	Bhaba Atomic Research Centre(BARC) approval in case study involves use of radioisotopes/ionizing radiations (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
22)	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>

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23)	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
24)	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
25)	Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26)	Ethics Committee clearance of other centres (Total No. : _____) (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
27)	Log of delegation of responsibility of the study team members – sample format enclosed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28)	Document Receipt Form (one copy)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29)	Current status of ongoing studies conducted by Principal Investigator	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30)	Documentation of CTIRI registration/any other WHO platform registry (whenever applicable) (one copy)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
31)	GCP training certificates of principal investigator and co-investigator(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32)	Any other documents submitted	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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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	Pending		
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)	Pending		

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**Annexure 4: Delegation Log/ Roles and Responsibility**

Study title

Assessment of fall risk and its contributing factors in patients and evaluate the practice adherence to fall prevention SOP among staff nurses at a selected hospital of Kolkata.

Name	Role	No.
Prof. Dr. Piyali Bose	Principal Investigator	1
Dakshina Singh Lohar	Co-Investigator	2
	Co-Investigator	3
	Co-Investigator	4
	Study coordinator	5
	Study coordinator	5
	Laboratory Technician	6

**Roles and Responsibilities assigned to Study Team**

CODE	TASKS	ROLE 1	ROLE 2	ROLE 3	ROLE 4	ROLE 5	ROLE 6
A.	All relevant documents pertaining to protect blinding	✓					
B.	Subject selection / screening		✓				
C.	Obtain informed consent		✓				
D.	Evaluate inclusion/exclusion criteria		✓				
E.	Conduct the visit assessments		✓				
F.	Physical examination		✓				
G.	Complete the source documents		✓				
H.	Complete and correct CRF		NA				
I.	Final review and sign CRF		NA				
J.	Collect laboratory safety test samples		NA				
K.	Processing blood samples		NA				
L.	Preparing aliquots & keeping a tract of the samples sent		NA				
M.	Review and signing of the laboratory reports		NA				

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N.	Receive the study drug, document drug, dispensing, storage & accountability		NA			
O.	Persons with whom subject should contact in case of adverse event		NA			
P.	Report all Serious Adverse Events (SAE)		NA			
Q.	Follow up of SAE		NA			
R.	Maintaining study site master file		NA			
S.	In-charge of inventory & supplies		✓			
T.	Archiving of study documents		NA			
U.	Resolution of queries		✓			
V.	Overall coordination and supervision	✓				

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