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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

	<b>Tata Medical Center Institutional Review Board</b>	SOP: TMC/IRB/SOP-13 Version No.: 13.1 Effective Date: 03-10-2025 To be reviewed (on or before): 31-03-2026
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**TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission**

Prepared by : Dr Indranil Mallick	Reviewed by: Prof Partha Pratim Majumder	Reviewed by: Dr Pattatheyil Arun
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution

**Annexure 1: INITIAL STUDY SUBMISSION FORM**

Section A: Title and Principal Investigator		
Study title	"A study to assess the effectiveness of a structured educational intervention on knowledge and attitude regarding menstrual hygiene among adolescent girls in a selected school of Howrah, West Bengal."	
	Name	Affiliation
Principal Investigator	Sniparna Guin	ANS cum professor
Co-Principal Investigator	Nasima Khatun	M.Sc Nursing 1 <sup>st</sup> year
Co-Principal Investigator		
Section B: Type of Study		
By Origin	<input type="checkbox"/> Industry Sponsored <input type="checkbox"/> Investigator Initiated	
Sponsor Details		
By Design	<input 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 type="checkbox"/> None of the Above (please specify intervention below)	

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<p><b>Type of intervention</b> Please select all the interventions applicable. The intervention may be an addition to or a modification of the current standard of care</p>	<p>Drug      Vaccine      Device Radiotherapy      Radioisotope Surgery Diagnostic test Supportive Therapy Educational Intervention Other</p>
<p><b>Is this a regulatory trial?</b> 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.</p>	<p align="center">Yes      No</p>
<p><b>Is this an investigational new drug (IND) or first in human drug study?</b></p>	<p align="center">Yes      No</p>

Section C: Centers and Participants	
Enrolling Centers	<p align="center">Single Center      Multicenter</p>
<p align="center">(for multicenter studies) <b>Number of participating centers</b></p>	
International enrolment	<p align="center">Yes      No</p>
Total planned sample size	
Estimated/ Planned enrolment at Tata Medical Center	

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<b>Will vulnerable subjects be enrolled</b>	<div style="display: flex; justify-content: space-between;"> <span>Yes</span> <span>No</span> </div> <p>(If Yes, Please Indicate)</p> <p>Children;      Employees of the Institute</p> <p>Patients, who are in Critical Care</p> <p>Economically/ Socially Backward</p> <p>Unable to understand written documentation</p> <p>Others</p>
<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.	<p>Consent Waiver Requested</p> <p>Standard Informed Consent form for Adult Subject</p> <p>Informed consent form for legally authorized representative (for all children and those adults incapable of consenting)</p> <p>Assent form (applicable for children between 7-15 in addition to informed consent for LAR)</p>
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>	Yes, I Confirm...
<b>Does your study have a Data and Safety Monitoring Committee (DSMC)?</b>	Yes                      No

<b>Section D: Funding, Insurance and Indemnity</b>	
<b>Total budget of the study (in INR)</b>	
<b>Who will fund the following</b>	


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Trial Intervention	Subject                      Industry Sponsor Institute as Sponsor                      NA
Cost of Serious Adverse Events	Subject                      Industry Sponsor Institute as Sponsor                      NA Sponsor may avail of Clinical Trial Insurance
Compensation for Trial Related Injury	Subject                      Industry Sponsor Institute as Sponsor                      NA Sponsor may avail of Clinical Trial Insurance
If the answer to any of the above questions is ' <u>Subject</u> ', 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.	Yes                      No

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<p><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.</p>	<p align="center">Yes                      No</p>
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**Section E: Special Considerations**


<p><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.</p>	<p align="center">No                      Yes</p>
<p><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_StemCellResearch2017.pdf">https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch2017.pdf</a></p>	<p align="center">No                      Yes</p>
<p><b>Does your project involve the use of infectious material?</b> If yes, please provide clearance from the Institutional Biosafety Committee (IBSC)</p>	<p align="center">No                      Yes</p>
<p><b>Does your project involve the use of radioactive isotopes?</b> If yes, please provide clearance from the appropriate governmental agencies.</p>	<p align="center">No                      Yes</p>
<p><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-intelligencein-biomedical-research-and-healthcare">https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligencein-biomedical-research-and-healthcare</a></p>	<p align="center">No                      Yes</p>

**Section F: Collaboration or sharing data/materials with external institutions or agencies**

<p><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></p>	<p align="center">No                      Yes</p>
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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>	Yes 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/healthministry-screening-committee-hmsc">https://main.icmr.nic.in/content/healthministry-screening-committee-hmsc</a>	Yes In Progress

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
Principal Investigator	Sniparna Guiri	<i>Sniparna Guiri</i>	9051297990 sniparna.giri@tmcokolkata.com
Co-PI Co-I	Nasima Khatun	<i>Nasima Khatun</i>	6295795987 nasimakhatunkhatun93@gmail.com
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			

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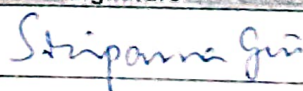
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TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission

Co-PI	Co-I			
Co-PI	Co-I			
Co-PI	Co-I			
Co-PI	Co-I			
Co-PI	Co-I			
Co-PI	Co-I			


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
Sniparna Ghosh		4.4.26
Click here to enter a date.		

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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Name and Signatures of Co-investigator(s) with Date		
Name	Signature	Date
Nasima Khatun	Nasima Khatun	04.04.2026

Name and Signatures of Head of Department(s) with Date		
Name	Signature	Date
Chitra Sengupta	Chitra Sengupta	4.4.26


Stamp/ Seal of the Department(s)

Prof. Chitra Sengupta  
Principal  
Tata Medical Center  
Kolkata

Annexure 2: Undertaking by the investigator as per Schedule III, Table 4 of NDCT (Third Amendment) Rules, 2022

Protocol Name:

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IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution

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


Sripurna Sin 4.4.24  
 8. Signature of the Investigator with Date Name  
 of the Investigator: SRIPARNA GIRI

**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	✓			
2)	Letter to Member Secretary/Chairperson	✓			
3)	Summary of protocol (in not more than 500 words)	✓			
4)	Protocol	✓			
5)	Amendments to protocol				
6)	Informed consent document in English	✓			
7)	Informed consent document in Regional languages (Total No. : )		✓		
8)	Back translations of Informed consent documents		✓		
9)	Translation and Back translation certificates of Informed consent documents		✓		
10)	Amendments to the Informed consent documents		✓		
11)	Case Record Form				
12)	Subject recruitment procedures : advertisements, notices		✓		
13)	Patient instruction card, identity card, diary etc.		✓		
14)	Patient/subject questionnaire(s) (No.:___)				

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

15)	Insurance policy (only one copy is needed for submission)				✓
16)	Investigator's undertaking to DCG(I) (one copy)				✓
17)	DCG(I) approval (one copy)				✓
18)	Investigator's agreement with sponsor (copy of final signed document)				✓
19)	DCG(I) marketing/manufacturing licence for herbal formulations/nutraceuticals (one copy)				✓
20)	Health Ministry Screening Committee (HMSC) approval, in case the study involves collaboration with any foreign laboratory/clinic/institution (one copy)				✓
21)	Bhaba Atomic Research Centre(BARC) approval in case study involves use of radioisotopes/ionizing radiations (one copy)				✓
22)	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (one copy)				✓
23)	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis (one copy)				
24)	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (one copy)				
25)	Signed and dated brief current curriculum vitae of the study team members (principal investigator, coinvestigator, study coordinator) (one copy)	✓			
26)	Ethics Committee clearance of other centres (Total No. : _____) (one copy)				
27)	Log of delegation of responsibility of the study team members – sample format enclosed	✓			
28)	Document Receipt Form (one copy)	✓			
29)	Current status of ongoing studies conducted by Principal Investigator	✓			
30)	Documentation of CTRI registration/any other WHO platform registry (whenever applicable) (one copy)				
31)	GCP training certificates of principal investigator and coinvestigator(s)	✓			
32)	Any other documents submitted	✓			

**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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IRB Member Secretary

TMC-IRB Chairperson

Head of the Institution



## Tata Medical Center Institutional Review Board

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Version No.: 13.1 Effective  
Date:

03-10-2025

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31-03-2026

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)			

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

IRB Member Secretary

TMC-IRB Chairperson

Head of the Institution

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


Study title

Name	Role	No.
Sripanna Giri	Principal Investigator	1
Nasima khatoon	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						
I.	Final review and sign CRF						
J.	Collect laboratory safety test samples						
K.	Processing blood samples						
L.	Preparing aliquots & keeping a tract of the samples sent						



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

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IRB Member Secretary

TMC-IRB Chairperson

Head of the Institution

N.	Receive the study drug, document drug, dispensing, storage & accountability								
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