



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	Reviewed by: Prof Partha Pratim Majumder	Reviewed by: Dr Pattatheyl Arun
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

Section C: Centers and Participants		
Enrolling Centers	<input checked="" type="checkbox"/> Single Center <input type="checkbox"/> Multicenter	
(for multicenter studies) Number of participating centers		
International enrolment		<input type="checkbox"/> Yes <input type="checkbox"/> No
Total planned sample size		
Estimated/ Planned enrolment at Tata Medical Center		
Will vulnerable subjects be enrolled	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, Please Indicate) <input type="checkbox"/> Children; <input type="checkbox"/> Employees of the Institute <input 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	
Informed Consent 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. https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx		<input checked="" type="checkbox"/> Yes, I Confirm...
Does your study have a Data and Safety Monitoring Committee (DSMC)?		<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 20000/-
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 ' <u>Subject</u> ', please explain below: 	
Does your trial have clinical trial indemnity for investigators? 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
Does the sponsor of the trial have clinical trial insurance? 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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Section D: Funding, Insurance and Indemnity

Total budget of the study (in INR)

INR 20000/-

Who will fund the following

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 'Subject', please explain below:

Does your trial have clinical trial indemnity for investigators?

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

Does the sponsor of the trial have clinical trial insurance?

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.

☐ Yes ☒ No

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TMC-IRB Chairperson

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Section E: Special Considerations		
<p>Does the project involve bio-banking any blood or tissue? 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>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>Does your project involve the use of stem cells? If yes, please make sure you are aware of the DBT-ICMR guidelines for Stem Cell Research. https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>Does your project involve the use of infectious material? If yes, please provide clearance from the Institutional Biosafety Committee (IBSC)</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>Does your project involve the use of radioactive isotopes? If yes, please provide clearance from the appropriate governmental agencies.</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>Does your project involve the development or use of artificial intelligence tools? If yes, please make sure you are aware of the ICMR guidelines for the 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</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Section F: Collaboration or sharing data/materials with external institutions or agencies		
<p>Does your project involve sharing of data, digital samples (images/sequencing data etc.) or biological samples of any form with any external institution/agency?</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>If yes, I confirm that there is a data/ material transfer agreement in consideration between the institution and external agency covering all of the following</p>	<p>Privacy Preservations</p> <p>Rights of access and use</p> <p>Safekeeping and archiving</p> <p>Disposal of digital and/ or biological material</p>	
<p>Does your project involve funding or collaboration with any foreign agency or institution?</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>If yes, do you have clearance from the Health Ministry Screening Committee (HMSC)? Please check the following for details: https://main.icmr.nic.in/content/health-ministry-screening-committee-hmsc</p>	<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
Principal Investigator	Prof. Dr. Piyali Bose	<i>Piyali Bose</i>	9433888242 piyali.bose@gmail.com
Co-PI Co-I	Pratyusha Roy	<i>Pratyusha Roy</i>	9064382718 smart2mam@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	<i>Piyali Bose</i>	Click here to add a date. 1/1/26

Name and Signatures of Co-investigator(s) with Date

Name	Signature	Date
Pratyusha Roy	<i>Pratyusha Roy</i>	04/04/2026


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

Name	Signature	Date
Prof. Dr. Piyali Bose		
Chitra Sengupta	<i>Chitra Sengupta</i>	4.4.26

Stamp/ Seal of the Department(s)

Prof. Chitra Sengupta
Principal
Tata Medical Center
Kolkata

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

Protocol Name:

1. **Full name, Address and Title of the Principal Investigator/** (Investigator(s) when there is no Principal Investigator)
2. **Name and Address of the medical college, hospital or other facility** where the clinical Trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial [Attach details including Curriculum Vitae, Good Clinical Practice Certificate & Medical Council Registration Certificate and/or any other statement(s) of qualification(s)].
3. **Name and Address of all clinical laboratory facilities** to be associated with the study.
4. **Name and Address of the Ethics Committee that is responsible for approval and continuing review of the study.**
5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).
6. **Protocol Title and Study number** (if any) of the clinical trial to be conducted by the Investigator.
7. **Commitments:**
 - ❖ I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
 - ❖ I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
 - ❖ I agree to personally conduct and/or supervise the clinical trial at my site.
 - ❖ I agree to inform all Subjects that the drugs are being used for investigation purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.
 - ❖ I agree to report to the Sponsor all adverse experiences that occur in the course of the study in accordance with the regulatory and GCP guidelines.
 - ❖ I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - ❖ I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
 - ❖ I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
 - ❖ I agree to promptly report to the IRB/EC all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
 - ❖ I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
 - ❖ I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
 - ❖ I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
 - ❖ I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of the Investigator with Date

Name of the Investigator:

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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 checked="" type="checkbox"/>		<input 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 type="checkbox"/>	<input checked="" 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 type="checkbox"/>		<input checked="" 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 CTRI 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 physical and psychological problems among patients undergoing hysterectomy in a selected hospital, Kolkata.
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Name	Role	No.
Prof. Dr. Piyali Bose	Principal Investigator	1
Pratyusha Roy	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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Annexure 5: Document Receipt form

Receipt No.			
Protocol Name			
Protocol No.		Submission Date	
Principal Investigator			
Department			
Communication	E-mail address:		
Documents submitted	Complete Incomplete, Will submit on:		
Documents to be submitted later	Final signed clinical trial agreement Informed consent form Case report forms (CRF) Study budget Investigator's brochure Insurance document Others (Please Mention)		

Name of Receiver

Signature:

Date:

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