



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



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

Annexure 1: INITIAL STUDY SUBMISSION FORM

Section A: Title and Principal Investigator	
Study title	Impact of Esophageal Sparing IMRT on patient reported dysphagia outcomes in patients of Non Small Cell Lung Cancer treated with Radical Radiotherapy with or without chemotherapy
Principal Investigator	Dr. Tapesh Bhattacharyya
Co-Principal Investigator	
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 checked="" type="checkbox"/> Drug <input type="checkbox"/> Vaccine <input type="checkbox"/> Device <input checked="" type="checkbox"/> Radiotherapy <input type="checkbox"/> Radioisotope <input type="checkbox"/> Surgery <input type="checkbox"/> Diagnostic test <input type="checkbox"/> Supportive Therapy <input 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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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	40	
Estimated/ Planned enrolment at Tata Medical Center	40	
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)

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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Section E: Special Considerations

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.

☐ Yes

☒ No

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

☐ Yes

☒ No

Does your project involve the use of infectious material?

If yes, please provide clearance from the Institutional Biosafety Committee (IBSC)

☐ Yes

☒ No

Does your project involve the use of radioactive isotopes?

If yes, please provide clearance from the appropriate governmental agencies.

☐ Yes

☒ No

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>

☐ Yes

☒ No

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

Does your project involve sharing of data, digital samples (images/sequencing data etc.) or biological samples of any form with any external institution/agency?

☐ Yes

☒ No

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

Privacy Preservations

Rights of access and use

Safekeeping and archiving

Disposal of digital and/ or biological material

Does your project involve funding or collaboration with any foreign agency or institution?

☐ Yes

☒ No

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>

☐ Yes

☒ In Progress

NA



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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			
Co-PI Co-I	DR. Tapesh Bhattacharyya	Tapesh Bhattacharyya	96565 70171 tapesh27@gmail.com
Co-PI Co-I	Dr. Moses Arun Singh		85moses@gmail.com
Co-PI Co-I	Dr. Urushi Thakur	Urushi Thakur	urushithakur.ut@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			



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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
Dr. Tapesh Bhattacharyya		05/05/26
Name and Signatures of Co-investigator(s) with Date		
Name	Signature	Date
Dr. Muneer Azeem Singh		
Dr. Urvasi Mukherjee		05/05/26

Name and Signatures of Head of Department(s) with Date		
Name	Signature	Date
Dr. Rimpa Basu Achari		05/05/2026

Stamp/ Seal of the Department(s)

Dr Rimpa Basu Achari
HOD & Senior Consultant
Dept. of Radiation Oncology
Tata Medical Center, Kolkata

Individually Attached



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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:

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 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 type="checkbox"/>	<input type="checkbox"/>		<input checked="" 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 type="checkbox"/>		<input checked="" 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. :)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
8)	Back translations of Informed consent documents	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
9)	Translation and Back translation certificates of Informed consent documents	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
10)	Amendments to the Informed consent documents	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
11)	Case Record Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input 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 type="checkbox"/>		<input checked="" type="checkbox"/>
15)	Insurance policy (only one copy is needed for submission)	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
16)	Investigator's undertaking to DCG(I) (one copy)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
17)	DCG(I) approval (one copy)	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
18)	Investigator's agreement with sponsor (copy of final signed document)	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
19)	DCG(I) marketing/manufacturing licence for herbal formulations/nutraceuticals (one copy)	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" 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 type="checkbox"/>		<input checked="" type="checkbox"/>
21)	Bhaba Atomic Research Centre(BARC) approval in case study involves use of radioisotopes/ionizing radiations (one copy)	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" 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 type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>
25)	Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
26)	Ethics Committee clearance of other centres (Total No. : _____) (one copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
27)	Log of delegation of responsibility of the study team members – sample format enclosed	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
28)	Document Receipt Form (one copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
29)	Current status of ongoing studies conducted by Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
30)	Documentation of CTIRI registration/any other WHO platform registry (whenever applicable) (one copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
31)	GCP training certificates of principal investigator and co-investigator(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
32)	Any other documents submitted	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 <i>Declaration</i>			✓
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)	✓		



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Annexure 4: Delegation Log/ Roles and Responsibility

Study title	Name	Role	No.
Impact of Esophageal Sparing IMRT on patient reported dysphagia outcomes in patients of Non-Small Cell Lung Cancer treated with Radical Radiotherapy with or without Chemotherapy	Dr. Tapesh Bhattacharyya	Principal Investigator	1
	Dr. Anshu Arun Singh	Co-Investigator	2
	Dr. Urvashi Thakur	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 track of the samples sent						
M.	Review and signing of the laboratory reports						

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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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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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:

Alexandre Nayam Chaudhry



Date:

05/03/2026