



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



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Annexure 1: INITIAL STUDY SUBMISSION FORM

Section A: Title and Principal Investigator		
Study title	A Phase 3, Multicenter, Open-Label, Randomized Trial to Compare the Efficacy and Safety of Elritcept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions.	
	Name	Affiliation
Principal Investigator	Dr. Arijit Nag	Clinical Hematology and Cellular Therapies
Co-Principal Investigator	Dr. Shouriy Ghosh	Clinical Hematology and Cellular Therapies
Co-Principal Investigator	Dr. Debranjani Chottopadhyay	Clinical Hematology and Cellular Therapies
Section B: Type of Study		
By Origin	☒ Industry Sponsored ☐ Investigator Initiated	
Sponsor Details	Takeda Development Center Americas, Inc.	
By Design	☐ Observational ☒ Interventional	
For Interventional studies only		
Phase of Study	☐ Phase I ☐ Phase II ☒ Phase III ☐ Phase IV ☐ Bioavailability/ Bioequivalence (BA/ BE) study ☐ Pre- Clinical Study ☐ 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	☒ Drug ☐ Vaccine ☐ Device ☐ Radiotherapy ☐ Radioisotope ☐ Surgery ☐ Diagnostic test ☐ Supportive Therapy ☐ Educational Intervention ☐ 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.	☒ Yes ☐ No	
Is this an investigational new drug (IND) or first in human drug study?	☒ Yes ☐ No	

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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Section C: Centers and Participants		
Enrolling Centers		☐ Single Center ☒ Multicenter
(for multicenter studies) Number of participating centers		
International enrolment		☒ Yes ☐ No
Total planned sample size		
Estimated/ Planned enrolment at Tata Medical Center		V
Will vulnerable subjects be enrolled	☐ Yes ☒ No (If Yes, Please Indicate) ☐ Children; ☐ Employees of the Institute ☐ Patients, who are in Critical Care ☐ Economically/ Socially Backward ☐ Unable to understand written documentation ☐ Others	
Informed Consent All consent forms must be submitted in English, Bengali and Hindi with valid translation and back-translation certificates before IRB review.	☐ Consent Waiver Requested ☒ Standard Informed Consent form for Adult Subject ☐ Informed consent form for legally authorized representative (for all children and those adults incapable of consenting) ☐ 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		☐ Yes, I Confirm...
Does your study have a Data and Safety Monitoring Committee (DSMC)?		☒ Yes ☐ No



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Section D: Funding, Insurance and Indemnity

Total budget of the study (in INR)

12,81,733/Per subject

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



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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	Dr. Arijit Nag		9051121161, arijit.nag@tmckolkata.com
Co-PI Co-I	Dr. Shourio Ghosh		9971505670, shourio.ghosh@gmail.com
Co-PI Co-I	Dr. Debranjani Chottopadhyay		9092536203, drdebranjani@gmail.com
Co-PI Co-I	Dr. Saswata Saha		9475241995, saswataonline@gmail.com
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. Arijit Nag		05.05.2026
Name and Signatures of Co-investigator(s) with Date		
Name	Signature	Date
Dr. Shourio Ghosh		05.05.2026
Dr. Debranjani Chatteropadhyay		05.05.2026
Dr. Saswata Saha		05.05.2026

Name and Signatures of Head of Department(s) with Date		
Name	Signature	Date
Dr. Jeevan Kumar		05.05.2026

Stamp/ Seal of the Department(s)

Dr. Jeevan Kumar
Senior Consultant,
Clinical Haematology and Cellular therapies
Tata Medical Center
Kolkata-700160, W.B.



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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	☒	☐		☐
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.:)	☒	☐		☐
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)	☐	☐		☒

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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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, co-investigator, 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 co-investigator(s)	☒	☐	☐
32)	Any other documents submitted	☐	☐	☒



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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	✓		
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: A Phase 3, Multicenter, Open-Label, Randomized Trial to compare the Efficacy and Safety of Elvitegravir versus Eposim Alfa for the Treatment of Anemia Due to IPSS-A Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions.

Name	Role	No.
Dr. Arijit Nag	Principal Investigator	1
Dr. Shourio Ghosh	Co-Investigator	2
Dr. Debranjani Chottopadhyay	Co-Investigator	3
Dr. Saswata Saha	Co-Investigator	4
Mr. Bibhas Chakraborty	Study coordinator	5
	Study coordinator	5
Not yet confirmed	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:

Date: