



**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**

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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4. One set of the protocol (original)

5.2.2 Verify contents of Submitted Package

The Secretariat will:

5.2.2.1 Use the checklist for contents of a submitted package, to verify that items listed and ticked in the checklist are present in the packet. Check if all relevant and applicable forms and documents are in the package being submitted to the IRB office. The correctness of the IRB application form will be assessed at the time of submission by the secretariat. Verify the completeness of the contents of the protocol submitted package to include the following documents:

- 1) -Project submission application form for initial review
- 2) -Letter to Chairperson/Member Secretary
- 3) -Protocol, to include
 - a) Title of the Protocol
 - b) Name and contact details of Principal Investigator
 - c) Name and contact details of Sponsor
 - d) Other reference numbers (if applicable)
 - e) Abstract (summary/synopsis)
 - f) Study Methodology ☐ Type of Protocol (screening, survey, phase of clinical trial), Objectives, Inclusion/Exclusion Criteria, Withdrawal or discontinuation Criteria, Schedule and Duration of Treatment, Modes of Treatment Studied, Procedures, Activity plan / Timeline, Efficacy or Evaluation Criteria.
 - g) (Response/Outcome), Safety Parameters Criteria (Toxicity), Analysis (methods) (Format as per Table 2 of NDCT (Third Amendment) Rules, 2022)
- 4) Amendments to protocol (if any)
- 5) Informed consent document in English
- 6) Informed consent document in Regional languages
- 7) Back translations of Informed consent documents-Back translation certificate
- 8) Patient Information Sheet (PIS) and Informed Consent Document (ICD) or Amendments to the PIS and ICD (if any)
- 9) Case Record Form (CRF)
- 10) Subject recruitment procedures: advertisement, notices, letters to doctors (if applicable)
- 11) Patient instruction card, identity card, diary etc. (if applicable)
- 12) Research Support Directorate (RSD) permission
- 13) Investigator Brochure (for regulatory studies)
- 14) Regulatory permissions (as applicable)
- 15) Central Licensing Authority (CLA) approval (as applicable)
- 16) Investigator's undertaking to CLA (if applicable)
- 17) Regulatory marketing/manufacturing license for herbal drugs
- 18) Health Ministry Screening Committee (HMSC) approval (for studies with international collaborators)
- 19) Bhabha Atomic Research Centre (BARC) approval (for studies involving radioisotopes)
- 20) Genetic Engineering Advisory Committee (GEAC) approval (if applicable)
- 21) Director General of Foreign Trade (DGFT) approval (if applicable)
- 22) Review Committee of Gene Manipulation (RCGM) approval (if applicable)
- 23) Administrative sanction in case of studies involving collaboration with other institutions
- 24) Principal Investigator's and Co-investigator's brief Curriculum Vitae
- 25) Investigator's agreement with Sponsor
- 26) Insurance and/or Indemnity policy
- 27) Ethics Committee clearance of other centres for collaborative studies (if applicable)
- 28) Any additional document(s), as required by IRB e.g. Information to Clinical Trial Registry India (CTRI website)
- 29) Investigator Undertaking (Please see Appendix)

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Continuing Review Application Form, Progress report/Request letter for extension of approval of the project. The Administrative Officer will sign and date the documents.

5.6 Study Completion

The Principal Investigator will electronically submit a Study Completion Report and related documents (See: TMC IRB SOP 10: Completion/ Termination of Study). The Secretariat will verify the completeness of the Study Completion Report Form filled by the Principal Investigator

Principal Investigator Co-Principal Investigator Study Completion Report	Study Completion Report Study Completion Report
Study Completion Report Study Completion Report	Study Completion Report Study Completion Report
Study Completion Report Study Completion Report	Study Completion Report Study Completion Report
Study Completion Report Study Completion Report	Study Completion Report Study Completion Report
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(for multicenter studies)		
Number of participating centers		7
International enrolment		Yes ☐ No ☒
Total planned sample size		78
Estimated/ Planned enrolment at Tata Medical Center		2-3
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 ☐

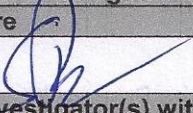
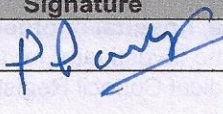
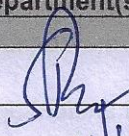
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Section E: Special Considerations		
Does the project involve bio-banking any blood or tissue? If bio-banking is planned at Tata Medical Center, please provide documentation that confirms that the TMC bio-bank and you are mutually aware of the requirements 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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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 Harmonisation ☐ Good Clinical Practices (ICH ☐ GCP) Guidelines (1996) while conducting the research study.

Name and Signatures of Principal investigator with Date		
Name	Signature	Date
Dr. Somnath Roy		01/06/2026
Click here to enter a date.		
Name and Signatures of Co-investigator(s) with Date		
Name	Signature	Date
Dr. Prashant Pandey		01/06/2026
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Click here to enter a date.		
Name and Signatures of Head of Department(s) with Date		
Name	Signature	Date
Dr. Somnath Roy		01/06/2026
Click here to enter a date.		
Click here to enter a date.		

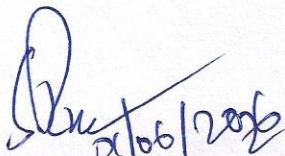
Stamp/ Seal of the Department(s)

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- ❖ 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.


21/06/2025

8. Signature of the Investigator with Date

Name of the Investigator:

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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, 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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Annexure 4: Delegation Log/ Roles and Responsibility

Study title	A prospective, observational, multicenters, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancers (NSCLC)						
	Name	Role	No.				
	Dr. Somnath Roy	Principal Investigator	1				
	Dr. Prashant Pandey	Co-Investigator	2				
		Co-Investigator	3				
		Co-Investigator	4				
	Souhita Pal	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	☐	☐	☐	☐	☐	☐
M.	Review and signing of the laboratory reports	☒	☐	☐	☐	☐	☐
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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1. Statement that the study involves research and explanation of the purpose of the Research
2. Expected duration of the Subject's participation.
3. Description of the procedures to be followed, including all invasive procedures.
4. Description of any reasonably foreseeable risks or discomforts to the Subject.
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).
9. Compensation and/or treatment(s) available to the Subject in the event of a trial related Injury.
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
11. The anticipated prorated payment, if any, to the Subject for participating in the trial.
12. Subject's responsibilities on participation in the trial.
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.
14. Any other pertinent information.

1.2 Additional elements, which may be required.

- a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
- b. Additional costs to the Subject that may result from participation in the study.
- c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
- d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
- e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.
- f. Approximate number of Subjects enrolled in the study.

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Child assent statement for children [>7 and <18] years (wherever applicable)

I have had the above research project explained to me in language that I can understand and I agree to participate.

Protocol Title:

Study Number:

Subject's Initials:

Study Number:

Subject's Name:

Date of Birth / Age:

Date:

Signature of child:

Date:

Name of person obtaining Signature of person:

Date:

Name of Legal Relation:

Relationship with Subject:

Signature:

Date:

Name of the Impartial Witness:

Name of the person/Signature of the person administering consent

Name of Principal Investigator

Contact Details of Principal Investigator

- Email ID:
- Contact Number:
- Address

Institutional Review Board (IRB) - Tata Medical Center

- Phone Number
- Email-ID:
- Address

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If the genetic study is being carried on as a sub-study, withdrawal from the genetic study should not affect participation in the main study. The participant should be given the right to request for destruction of his/her sample provided the sample has not been anonymous till that time.

H. Confidentiality

The participant should be informed whether the samples are to be unidentified, unlinked or coded as defined in the ICMR Guidelines, 2017. If the investigator does not intend to disclose the results of the study (for example, in the case of a preliminary/pilot study), the samples should be 'anonymous.' If the investigator intends to disclose the results of the genetic testing, the participant should have the right to decide whether or not he desires such disclosure. Family members are not entitled to know each other's diagnosis and specific consent is needed from a participant before sharing the information with family members. It is the duty of the investigator to explain in detail the consequences of revelation of the genetic test prior to revealing the results.

Example: The investigator will provide the genetic analyses to your family, the doctor conducting the main study or any doctor involved in your care, your insurance company or your employer, only after obtaining your written consent. However, this is subject to the requirement of disclosure of such information to a court of law. It may also be made accessible to members of ethics committees and regulators."

Annexure 8: Assent form for children: TMC studies

An Informed Assent Form doesn't replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

For children between 7 and 12 years of age, oral assent must be obtained in the presence of parent/LAR. For children between 12 and 18 years of age, written assent must be obtained. If a child becomes 13 years old during the course of the study, then written assent must be obtained in addition to parent/LAR consent. If the child becomes an adult then proper written consent should be obtained.

PART 1. The type and amount of information given should be simplified as per the child's cognitive and developmental level. The information should be simple, age-appropriate and in a language which the child can understand. The basic information that needs to be provided includes:

1. What the study is about and how it might help?

- A. "We want to see whether a new medicine will help children like you who have blood cancer".
"We want to understand why children get this cancer, like you do"

2. What will happen and when?

- A. "You will have to come to the hospital in the morning with an empty stomach. We will give you medicines through the small veins in your hand"

3. What discomfort there might be and what will be done to minimize it?

- A. "You may get some vomiting and weakness but we will try to decrease these problems with medicines"

4. Who will answer, if I have any questions during the study?

- A. If you have any questions, you can ask Dr X, any time."

5. Whether an option to say "no" exists?

- A. "You can say "no" if you don't wish to take part in the study. No one will be angry with you." "If you say "yes" initially and then change your mind later, it will be fine. No one will scold you and your treatment will continue as it was earlier".

Information on the Trial Drug [Name of Drug]

What is this drug and what do you know about it?

❖ Include the following section only if the protocol is for a clinical trial:

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Consent of Parent/LAR

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.
2. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.
3. Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.
4. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.
5. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.
6. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.
7. Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

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- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
- Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the EC, for example, in behavioural studies in IV drug users where parental consent may not be possible

Annexure 9: Procedure for taking informed consent

1.0 Purpose:

- 1.1 To mandate and elaborate the process of the voluntary consent of the human subjects in clinical research
- 1.2 To protect the freedom of choice of study participants
- 1.3 To discuss the relevant processes of consent dialogue and the documentation of obtaining informed consent on the IRB approved consent forms.

2.0 Scope:

- 2.1 This policy applies to all clinical, epidemiological, and academic and laboratory based research projects involving human participants; conducted under the purview of Tata Medical Center IRB.

3.0 Responsibility:

- 3.1 IRB – EC
- 3.2 IRB Secretariat
- 3.3 Principal Investigator(s) and Co-investigator(s)

4.0 Abbreviations:

IRB: Institutional Review Board

ICF: Informed Consent Form

EC: Ethics Committee

PIS: Patient Information Sheet

TMC: Tata Medical Center

5.0 Policy:

- 5.1 This policy mandates that an investigator shall obtain informed consent; written or verbal (as applicable); by providing the study participant or his/her representative sufficient opportunity to understand and consider the risks and benefits of the study and whether or not to take part in the study.
- 5.2 The policy intends to minimize the possibility of coercion or influence on the study participant(s) by ensuring a detailed dialogue between the researcher and the participant about the risks and benefits of any intervention.

6.0 Procedure:

- 6.1 The researcher shall obtain written or verbal (as applicable) informed consent from the study participant for any health research involving human participants.
- 6.2 The informed consent process involves three main components (ICMR, 2017): providing relevant information to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation.
- 6.3 **The following pre-requisites shall be ensured by the research team prior to taking informed consent (ICMR, 2017):**

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Tata Medical Center Institutional Review Board

SOP: TMC/IRB/SOP-13

Version No.: 13.1

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31-03-2026

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

- 6.8.1 When new information related to the study becomes available; relevant information with implications for the study participant shall be included in re-consenting.
- 6.8.2 The status of study participants change during the course of the trial; as a minor becomes an adult, a non-competent participant becomes competent.
- 6.8.3 When the treatment modality changes
- 6.8.4 When the research design changes; such as a change in the data collection method, site visits.
- 6.8.5 Any other change such as consent from a partner, possible disclosure of research information.

6.9 Consent for vulnerable groups:

Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests. A special care should be taken to prevent any harm to this group of population while doing a study involving them. The PIS and the Consent form should be carefully reviewed by the IRB before its approval.

The vulnerable population identified under the scope of this policy is detailed in TMC/IRB/SOP-24

8.0 Appendices:

- 8.1 Essential and additional elements of an informed consent document [ICMR guidelines, 2017. Schedule III Table 3 of NDCT (Third Amendment) Rules, 2022].

- 8.2 Conditions for granting waiver of consent: (ICMR, 2017)

The EC may grant consent waiver in the following situations:-

- 1) research cannot practically be carried out without the waiver and the waiver is scientifically justified
- 2) Retrospective studies where the participants are de-identified or cannot be contacted.
- 3) Research on anonymized biological samples/ data
- 4) Certain types of public health studies/surveillance programs /programme evaluation studies.
- 5) Research on data available in the public domain or
- 6) Research during humanitarian emergencies and disasters when the participants may not be in apposition to give consent. Attempts should be made to obtain the participants consent at the earliest.

Reference:

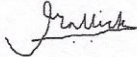
- ICMR guidelines 2017. ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 .
- New Drugs and Clinical Trials (Third Amendment) Rules, 2022.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTEzOQ
- Declaration of Helsinki 2013. GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3)
- NABH Accreditation Standards for Clinical Trial (Ethics Committees) 1st Edition: Explore NABH Standards - National Accreditation Board for Hospitals and Healthcare Providers (NABH) . .
- Council for International Organisations of Medical Sciences (CIOMS). Bioethics - CIOMS.
- ICH-GCP (E6) R3 06 January 2025. Efficacy Guidelines.

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

Signature

 Sep 27 2025 12:44 IST	 Sep 27 2025 13:41 IST
Dr Indranil Mallick Member Secretary	Prof. Partha Pratim Majumder Chairperson

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