INSTITUTIONAL ETHICS COMMITTEE
TOPIWALA NATIONAL MEDICAL COLLEGE & BYL NAIR CH. HOSPITAL,
'G'BUILDING, 4th FLOOR, DR A.L. NAIR ROAD, MUMBAI- 400008
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STANDARD OPERATING PROCEDURES (General)
REVISED VERSION Dated 22nd June 2026

1. NAME: The name of the Institutional Ethics Committee shall be `INSTITUTIONAL ETHICS COMMITTEE OF TOPIWALA NATIONAL MEDICAL COLLEGE AND B.Y.L. NAIR CHARITABLE HOSPITAL, MUMBAI '. Hereafter, the committee will be referred to as IEC.

2. PURPOSE, SCOPE & RESPONSIBILITY-

The purpose of this SOP is to ensure the effective functioning of the IEC by establishing a high-quality and consistent mechanism for the ethical and scientific review of all health and biomedical research proposals considered by it.

Biomedical research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records and biological samples as well as epidemiological, social, psychological and similar research.

These SOPs are applicable to all the externally sponsored research proposals other than investigator initiated / dissertation / academic projects that bare to be carried out at this institution.

Hon Member Secretary on behalf of the IEC is responsible for implementing this SOP.

3. ROLE OF IEC:

i. IEC will carry out the ethical and scientific review of biomedical and health research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants.

ii. The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non–maleficence and Justice are taken care of during the planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate treatment and compensation wherever required.

iii. It will review the proposals before the start of the study as well as monitor the proposed research periodically and after completion of the study by way of documented procedures.

iv. IEC will also examine compliance with all regulatory requirements, applicable guidelines and laws.

4. COMPOSITION OF THE IEC:

The IEC shall be multidisciplinary and multi sectorial in composition.

There shall be a minimum 7 to maximum 15 members in the IEC. The Chairperson of the Committee shall be from outside the institution. The Member Secretary shall be from within the institute and shall conduct the business of the IEC.

All the members including the Chairperson and the Member Secretary shall be appointed by the Dean of the institute based on their competencies and integrity

IEC will consist of 7 to 15 members from the following categories

1. Chairperson – One Person from outside the institution (preferably a medical scientist)
2. Secretary - One Medical scientist / Clinician from within the institute
3. Member - One or more Lay person from the community
4. Member - One or more Legal expert
5. Member - One or more Non-scientific person such as social worker/representative of the non-governmental voluntary organisation / ethicist / theologian / philosopher or a similar person

The other members forming the total composition should have good mix of institutional and non-institutional members. At least 50% of members should be non-institutional (external) members. There should be at least one pharmacologist and two medical scientists/clinicians in the committee. There should be adequate representation of different age groups, genders and communities in the IEC to safeguard the interest and welfare of all sections of the community/society.

The Dean if deemed necessary will appoint one more alternate member(s). The alternate member(s) will substitute one or more member(s) and attend the meeting in absence of the regular member(s). The alternate member(s) will have the same duties and responsibilities as the regular member(s). Medical scientist and clinician should have P.G. qualification.

If required subject expert/s may be invited to give their views.

5. AUTHORITY UNDER WHICH IEC IS CONSTITUTED:

The Dean of the institution constitutes the IEC.

6. MEMBERSHIP REQUIREMENTS:

i. The Dean will invite the members to join IEC by sending an official appointment letter.

ii. The members will confirm their acceptance to the Dean by providing all the required information for membership.

iii. The duration of appointment of the Chairperson, Secretary and IEC members will be for a tenure of 3 years and can be reappointed further for 3 years as suggested and approved by Dean and Chairperson.

iv. A member can be replaced in the event of death or long-term non-availability (if absent for $\geq$ 5 meetings in a year) or for any action not commensurate with the responsibilities laid down in the guidelines (National Ethical Guidelines for Biomedical & Health Research involving Human participants, ICMR, 2017) deemed unfit for a member

v. A member can tender resignation from the IEC with reason to do so and shall give at least one month notice. The letter of resignation should be addressed to the Dean and forwarded by the IEC Secretary.

vi. All members shall maintain confidentiality of all discussions during the meeting. Confidentiality agreement should be signed by the members at the time of appointment and renewal of appointment.

vii. Conflict of interest should be declared by the members of IEC.

viii. All members should undergo orientation program and training in national and international developments in bioethics / GCP once in every 3 years.

ix. If the member remains absent for 3 consecutive meetings without informing and giving a valid reason then the member can be ~~disqualified~~ discontinued.

x. No internal IEC members will be given any remuneration, but in special cases remuneration can be given by approval of the Chairperson and Dean.

xi. In special cases like epidemics, disaster, the IEC meetings will be taken via online platforms (video or audio modes) as available. Participation by Audio-Video or telephonic mode in such special expedited meetings will be granted as presence of members in such meeting. In case of online meetings, the cameras of the members should be kept on and screenshot of the members present would be taken for regulatory purposes. Such online meeting would be recorded.

7. QUORUM REQUIREMENTS

For review of each protocol the quorum of Ethics Committee should be at least 5 members with the following representations:

i. basic medical scientists (preferably one pharmacologist).
ii. Clinician.
iii. legal expert.
iv. social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person.
v. lay person from the community.

If the Chairperson is absent then an alternate Chairperson shall be elected by the members present for the meeting from any of the member from outside the institute who shall conduct the meeting.

8. OFFICE:

Institutional Ethics committee office will operate from the following address:

INSTITUTIONAL ETHICS COMMITTEE,
Topiwala National Medical College and B.Y.L. Nair Ch. Hospital,
G Building, 4th Floor, Dr. A. L. Nair Road,
Mumbai Central, Mumbai – 400 008.
Tel. No. 022-23027207 (Direct) or 23027000 ext. 7207
Email ID: nairethics@gmail.com

Official communication by IEC will be IEC mail / hard copy / WhatsApp (Only amongst members for fast communication).

Secretariat will consist of adequate number of qualified and competent staff to assist the member secretary.

The Member Secretary shall be responsible for organizing the meeting, maintaining the records and communicating with all concerned stakeholders. The secretariat shall prepare the minutes of the meetings and send the minutes by email to all members 14 days before the next meeting. The Member Secretary should get the minutes approved in the next IEC meeting by all IEC members and obtain the Chairperson's signature on the approved minutes.

In absence of the Member Secretary an internal member will hold charge temporarily.

9. INDEPENDENT CONSULTANTS

IEC may call upon Subject Experts as independent consultants who may provide special review of selected research proposals if need be. These experts may be specialists in medical specialties, ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views in writing but they will not have right to vote which will be made by the members of the IEC only.

10. APPLICATION PROCEDURE

i. All research proposals should be submitted in the prescribed application form, the details of which are given under documentation.

ii. All relevant documents should be enclosed with application form.

iii. Six copies and a soft copy of the proposal along with the application and document in prescribed format duly signed by the Principal Investigator/Co-investigator/ Collaborators should be forwarded to the IEC with a covering letter signed by the Head of the department. All IEC documents properly and neatly labeled and indexed should be submitted in the IEC office and the acknowledgement of submission should be taken from CCT of IEC.

iv. All the new proposals should be received at least 14 days and reply to the IEC query & amendments 5 days before the date of the next IEC meeting.

v. Every Research proposal will be allotted an IEC registration number to be used for all future correspondence and reference.

vi. The date of the next meeting will be decided in the previous meeting and the date will be displayed in the IEC office.

vii. PI should attend the IEC meeting and give a short power point presentation of the research project in the meeting after which the project will be discussed with the PI. If the PI is unable to attend the IEC meeting, then he should submit a letter to IEC mentioning the reason for not attending and the name of the Co-PI who would attend on his behalf.

viii. PI should be from this institute and the site of the study will be T.N.M.C. & B.Y.L. Nair Ch. Hospital.

ix. If the proposal is not complete then the secretarial has the right to not accept the incomplete proposal.

x. The IEC review charges for the various sponsored projects are as follows:

Type of Research Project	Ethics Review Charges (Excluding TDS)	Continuation charges beyond one year (Excluding TDS)
Industry sponsored projects	Rs. 80,000/-	Rs.12,000/-
	Reply to the IEC query letter after 3 months and before 6 months from date of receiving the IEC query letter.	Rs. 10,000/-
Sponsored projects concerned with diagnostic kits or projects with budget less than Rs 2.5 lakhs	20% of the budget	10% of the budget Or Rs.12,000/- whichever is less.
ICMR and Government Sponsored a) Interventional Project	10% of the total budget or Rs.80,000/- whichever is less.	5% of the budget or Rs.12,000/- whichever is less.
b) Other projects	5% of the budget or Rs.36,000/- whichever is less	2.5% of the budget or Rs.6,000/- whichever is less.

- In special case like Govt. Of India project review charges can be waived by Dean TNMC.

11. DOCUMENTATIONS

For thorough and complete review, all research proposals should be submitted with the following documents:

i. Invitation letter from Sponsor to the Principal Investigator to do the study.

ii. Application form (Application letter of Principal Investigator signed by HOD of

the department).

iii. Summary sheet

iv. Study protocol

v. Case Record Form (CRF)

vi. Patient information Sheets in suitable languages (English, Marathi and Hindi) as necessary.

vii. Informed Consent Form (ICF) in suitable languages (English, Marathi and Hindi) as necessary.

viii. Assent form in suitable languages (English, Marathi and Hindi) when research involves children aged 12 to 18 years.

ix. Translation certificate and Back Translation certificates of the Informed Consent Documents.

x. Additional documents such as questionnaires, patient diary card, advertisement for recruitment of study participants etc. as applicable.

xi. Investigator Brochure in case of new drugs. The information on the new drug. must contain animal toxicity data, pharmaceutical data, pharmacokinetic data in animals/humans and previous human experience with the drug.

xii. Tripartite Clinical trial Agreement between the PI, Sponsor and the Institution.

xiii. Professional Indemnity Policy indemnifying the PI and the Institution clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk. If indemnity policy is not available then an undertaking by the Sponsor should be submitted by the PI. Failure to submit this undertaking shall be liable for postponement of project review.

xiv. Source of funding and financial requirements for the project.

xv. Insurance liability copy and compensation policy for SAE occurring during the study. (Complete Insurance Policy document along with Insurance certificate).

xvi. Curriculum Vitae of PI and GCP training certificate of all investigators.

xvii. Regulatory permissions i.e. DCGI permission, HMSC permission (for International trials), if applicable.

xviii. Undertaking by the investigator given to DCGI and IEC.

xix. CTRI number in case of clinical trial

xx. Statement of conflict of interest, if any.

xxi. Any other information relevant to the study.

xxii. Delegation of log of duties.

xxiii. Whenever applicable letter of waiver of consent should be submitted.

xxiv. Administrative sanction from the Dean to conduct the research study in this institution.

xxv. Cheque Payment or online payment (with proof of the same) of IEC Review charges.

Please note that incomplete summary sheet and proposal will not be accepted.

12. REVIEW PROCEDURES

i. The meeting of the IEC will be held on scheduled intervals. IEC shall hold regular meeting once every month except during summer (May) and winter (October) vacations. The dates of the meeting should be fixed by the Member Secretary in consultation with the Chairperson and other members of the Committee.

ii. No Research projects will be accepted for review unless and until the necessary IEC review charges has been paid except for special cases like Govt. projects. The study related documents will not be accepted if all the required documents do not comply with the check list necessary for review of study protocol.

Office secretariat shall check all documents submitted before distribution to the members.

iii. The research proposal should be sent to the members at least 10 days before the next meeting for high quality review by members.

iv. Decisions will be taken by consensus after discussion of the research proposal. However, if needed, in the absence of consensus, voting will be taken where all members except the Chairperson will cast their vote. In case of a tie, the chairperson may either cast a deciding vote or postpone the decision to the next meeting.

v. Principal Investigator will be invited telephonically by CCT of IEC to attend the IEC meeting for Project related discussion with IEC and to offer clarifications if required. Principal Investigator will have to make a short power point presentation of the research proposal in the IEC meeting. It is compulsory for the Principal Investigator to be present for IEC meeting when Principal Investigators research proposal is discussed. In the absence of Principal Investigator, he /she should inform the IEC in writing stating the reason for his/her absence along with the details of the person who will presenting the project before the meeting. IEC may or may not accept the request depending upon the nature of the research proposal.

vi. Independent consultants/experts may be invited to offer their opinion on specific research proposals, if needed.

vii. All-important discussion /relevant discussion will be minuted. The decision will be

minuted and the Chairperson's approval taken in writing.

viii. All reply to IEC queries (unless decided by the members that these should be reviewed and discussed at the regular IEC meeting) will be examined by minimum 3 members decided by the Chairperson/ Member Secretary and if satisfactory the project approval can be given.

13. ELEMENTS OF REVIEW: Following points will be considered while reviewing the research proposals

i. Scientific design and conduct of the study.
ii. Examination of predictable risks/harms.
iii. Examination of potential benefits.
iv. Examination of risk benefit analyses.
v. Procedure for selection of participants in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
vi. Vulnerable participants: The examples of vulnerable participants are children, those with cognitive impairment, unconscious participants, students, certain ethnic groups, individuals which have hierarchical relationships. Such participants could be included in the research only when the research is directly answering health needs of the group.
vii. Management of research related injuries, adverse events.
viii. Compensation provisions.
ix. Justification for placebo in the control arm, if any.
x. Availability of products after the study (Post trial access of the IP), if applicable.
xi. Participant/Patient information sheet and informed consent form in local languages and provisions for taking appropriate informed consent process.
xii. Protection of privacy and confidentiality.
xiii. Involvement of the community, wherever necessary.
xiv. Plans for data analysis and reporting.
xv. Adherence to all regulatory requirements and applicable guidelines.
xvi. Qualification and Competence of investigators, research and supporting staff.
xvii. Facilities and infrastructure of study sites.
xviii. Criteria for withdrawal of patients, suspending or terminating the study.
xix. Use of disposal of stored or leftover biological samples for future research.

14. EXPEDITED REVIEW

IEC will receive and consider the proposals for expedited review and approval for the studies having involving

i. No or less than minimal risk to the trial participant.
ii. Re-examination of a proposal already examined by the IEC.
iii. Study of minor nature like the examination of case records.
iv. An urgent proposal on national interest having minimum risk.
v. Research involving non-identifiable specimen and human tissue from sources like blood bank, tissue banks and leftover clinical samples.
vi. Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researchers.

All revised proposals for expedited review unless specifically required to go through the regular meeting will be reviewed by minimum 3 members decided by the Chairperson/ Member Secretary. All the three members including the Member Secretary would discuss the proposal via electronic communication. Decision taken by the 3 members on expedited approval will be brought to the notice of the remaining committee members at the next regular meeting of IEC.

15. DECISION MAKING

i. Members will discuss the various issues before arriving at a consensus decision
ii. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be intimated to the Chairperson prior to the review of the application and recorded in the minutes.
iii. Decisions will be made only in meetings where quorum is complete.
iv. Only IEC members who participated in the review and discussions can make the decision. The expert consultants, if present, will only offer their opinion and they cannot vote.
v. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given. Revision of proposal may be necessary in case of proposals filled incompletely or incorrectly.
vi. In cases of conditional decisions, clear suggestions for revision will be conveyed to the Principal Investigator. Reply letter from PI in response to queries will be

reviewed by the Member Secretary or 3 members decided by the Chairperson / Member Secretary or the full board in the meeting and a decision will be taken.

vii. Approval of a proposal shall be valid for a period of one year. IEC shall charge fees of Rs 12,000 (excluding T.D.S.) per year for the continuation in case of sponsored research projects.

16. COMMUNICATING THE DECISION:

i. Decision will be communicated by the Member Secretary in writing (in the form of Approval letter or Query letter) within 14 days from the date of the meeting.

ii. Approval decision will be communicated in a specified format.

iii. Suggestions for modifications, if any, will be sent by IEC as Query letter.

iv. Reasons for rejection will be informed to the Principal Investigator.

v. The decision letter shall contain the following information:

1. Date and time of IEC meeting
2. Place of the meeting.
3. Names and designations of the Chairperson and members who attended the meeting.
4. Title of the research proposal.
5. Name of the Principal Investigator
6. List of documents (with date and version number wherever possible) reviewed by the IEC.
7. A clear statement of the decision reached.
8. Any advice or observations by the IEC.
9. In the case of Negative decision, reasons for not approving the proposal will be mentioned.
10. In the case of project Approval, the following responsibilities of the principal investigator must be communicated:
    a. Acknowledgement of receipt of the letter of approval.
    b. The approval is valid for one year from the date of issue of the Approval letter and if the project continues beyond a year, the principal investigator must apply to IEC for Extension of IEC approval prior to the expiry of IEC approval along with the current status report of the project.
    c. Any change / amendments in the protocol or standard recording documents should be intimated to the IEC for information and approval. Even the

administrative changes must be informed to IEC. PI should submit Summary of Changes in the amendment and highlight the same. Kindly note that the proposal without the summary of changes document would not be accepted for review.

d. All serious adverse events during the study should be reported to the IEC within 24 hours. and the Principal Investigator should take appropriate measures to manage the SAE.

e. The Principal Investigator has to reply to the IEC queries within a period of 3 months of receiving the IEC query letter or as specified by IEC. If the reply is submitted after 3 months but before 6 months of receiving the query letter, then the reply would be accepted with late fee charges of Rs 10,000/- (Rs ten thousand only). If reply is not submitted to IEC within 6 months, the project will be closed and after 6 months, the same project will be considered as a new project and IEC review charges will have to be paid again.

f. The validity of the approval is for a period of one year. After approval, projects should be initiated at the earliest. For projects not initiated within one year of approval, continuation of approval may be given for one more year on payment of applicable IEC charges (Rs 12,000/-) and submission of justification for late initiation of the project along with relevant updated data if any. If the project is not initiated within 24 months of initial approval, no further continuation shall be granted and the approval shall lapse.

g. In the case of study related injury /disability/ death of a research participant, the responsibility of compensation /treatment will rest on the Sponsor / Principal Investigator of the trial as per the law.

h. The principal investigator should intimate to the IEC within 1 week if the trial is terminated and the reasons for doing so.

i. The final report including the results of the research should be communicated to the IEC within 6months of completion of the project

j. The investigator shall be responsible to protect the dignity, rights, safety and well being of all research participants.

k. Investigator must obtain from Sponsor any new information that may affect the risk/benefit ratio of the research project and intimate the same to IEC at the earliest. IEC reserves the right to change the decision on the project in the light of any new information obtained.

17. FOLLOW UP PROCEDURE

i. IEC will periodically review the progress of all the studies for which IEC approval has been given. IEC will review status report once in a year and IEC may also conduct onsite monitoring.

ii. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in some special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and unwanted events happened during conduct of research project.

iii. All on site Serious Adverse Events (SAEs) should be intimated to the IEC within 24 hours of knowing the occurrence. All on site SAEs should be reported in a specified format (Table 5 as per NDCT rules 2019) mentioned in the separate SOP for managing the SAEs at this institute. The SAE committee will consist of one basic medical scientist and two scientific clinicians. The SAE committee member will review SAE's and their comments will be forwarded to regulatory authority within prescribed time limit.

iv. In case of SAEs (Serious Adverse Events) occurring in the clinical trial participants the principal investigator, after due analysis shall forward the SAE report to the licensing authority, the Chairperson of the IEC and Head of the institution within 14 calendar days of occurrence of the Serious Adverse Event.

v. In case of Serious Adverse Events occurring to the clinical trial participants, the IEC shall forward its report on the Serious Adverse Event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor, who had obtained permission from the licensing authority for conducting the clinical trial, to the Licensing authority within 30 calendar days of the occurrence of the Serious Adverse Event.

vi. In the case of the study related injury / disability/ death of a research participant, the responsibility of compensation /treatment will rest on the Sponsor of the trial.

vii. Any amendment to the protocol should be submitted for IEC approval.

viii. Protocol deviation, if any, should be informed with adequate justifications in prescribed format.

ix. Any new information related to the study should be communicated that may affect the benefit/risk ratio of the study.

x. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

xi. Principal Investigator must submit completion report along with the summary of the data obtained.

xii. Final report of the study should be sent to the IEC within a period of 6 months of completion.

xiii. Change of investigators at our site should be informed to IEC within a week.

xiv. IEC Secretary shall send reminder to the PI one month before expiry of 1 year from the approval date of the project, to apply for renewal / extension of the project. If PI does not renew or ask extension of the project within 3 months of expiry of 1 year then project will be assumed to be closed / terminated.

18. RECORD KEEPING AND ARCHIVING:

Following documents will be filed and archived with proper label on the top of file for easy identification

i. The constitution / written standard operating procedures of the IEC
ii. Curriculum Vitae (CV) of all members of IEC.
iii. The agenda of the IEC meetings
iv. Minutes of all meetings duly signed by the Chairperson.
v. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments
vi. One copy of all documents related to the study protocols, progress reports and SAES.
vii. All written documentation received during the follow up.
viii. Copy of all correspondence with members, researchers and other regulatory bodies.
ix. Final summary/ report of the approved projects.
x. All documents related to the research proposal should be archived for prescribed period 5 years after the completion/ termination of the project.

19. UPDATING IEC MEMBERS:

i. All relevant new guidelines should be brought to the attention of the members.

ii. Members shall be encouraged to attend National and International training program in research ethics for maintaining quality in ethical review and be aware of the latest development in this area.

iii. IEC shall organize and conduct GCP training program for IEC members and investigators at least once in every 3 years.

20. **Audio Visual Recording of the Informed Consent:**

In addition to obtaining written informed consent, audio-visual recording if applicable to the informed consent procedure of each trial participant and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation should be preserved by the Principal Investigator for a minimum period of 5 years after completion of the study.

The above Standard Operating Procedures (General) Revised version have been reviewed and approved by the IEC in its meeting held on 22nd June 2026.

22/6/26

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