INSTITUTIONAL ETHICS COMMITTEE
TOPIWALA NATIONAL MEDICAL COLLEGE & BYL NAIR CH. HOSPITAL,
'G'BUILDING, GROUND FLOOR, DR A.L. NAIR ROAD, MUMBAI- 400 008
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STANDARD OPERATING PROCEDURES (General) REVISED VERSION Dated 31st January 2019.

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 establish effective functioning of the IEC so that a quality and consistent ethical***and scientific***review mechanism for health and biomedical research is put in place for all proposals dealt by the IEC.

Biomedical research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical record 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*** submitted to IEC and to be carried out at this institution.

Member secretary ***on behalf of 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 in 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***compensations wherever required.

iii. It will review the proposals before 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 requirement, applicant guidelines and laws.

4. COMPOSITION OF IEC:

IEC shall be multidisciplinary and multisectorial in composition.

There shall be ***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 chairperson and 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 - OneMedical 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 non-governmental voluntary agency/ ethicist/theologian/philosopher or a similar person

The other members forming the total composition should have good mix of institutional and non-institutional members. There should be at least one pharmacologist and two medical scientists/clinicians in the committee. There should be adequate representation for 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).

If required, subject expert 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 the 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 will be for a tenure of 3 years and can be ***extended further.***

iv. A member can be replaced in the event of death or long term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member

v. A member can resign from the IEC giving valid reasons to do so and shall give intimation for resignation at least one month in advance. The letter of resignation should be addressed to the Dean***and forwarded by the IEC.***

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.

7. QUORUM REQUIREMENTS

For review of each protocol the quorum of Ethics Committee should be atleast 7members with the following representations:

i. Chairperson.

ii. Member Secretary.

iii. basic medical scientists (preferably one pharmacologist).

iv. Clinician.

v. legal expert.

vi. social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person.

vii. lay person from the community.

If the chairperson is absent then 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:

InstitutionalEthics committee office will operate from the following address :

INSTITUTIONAL ETHICS COMMITTEE,

Topiwala National Medical College and B.Y.L. Nair Ch. Hospital,

G Building, Ground Floor, Dr. A. L. Nair Road,

Mumbai Central, Mumbai – 400 008.

Tel. No. 022-23027207 (Direct) or 23027000 ext. ***7207***

Fax No. 022-23075243 (c/o Dean TNMC)

EmailID: nairethics@gmail.com

Official communication by IEC will be byemail / hard copy / What's app (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***. ***Member secretary shall prepare the minutes of the meetings and send the minutes by EMAIL to all members before the next meeting.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 membersecretary, an internal member will hold charge temporarily.

9. INDEPENDENT CONSULTANTS :

IEC may call upon subject expert as independent consultants who may provide special review of selected research proposal, if needed. These experts may be specialists in ***medical specialities***, 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. Eleven copies 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 labelledand indexed should be submitted in the IEC office and the acknowledgement of submission should be taken from CCT of IEC.***

iv. All the proposals should be received ***at least 20days***before the date of the next IEC meeting.

v. Every ***Research proposal*** will be allotted an IEC registration number which is 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. ***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 compulsary for the Principal Investigator to be present for IEC meeting when Principal Investigators research proposal is discussed. In the absence of Principal Investigator, the research proposal will not be discussed and the discussion of the research project will be postponed to the next IEC meeting.***

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

ix. 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)
1) Industry sponsored	***Rs.60,000/-***	***Rs.12,000/-***

projects.		
2) 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.
3) ICMR and Government Sponsored		
a)Interventional Project	10% of the total budget or ***Rs.60,000/-*** 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.

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 7 years and above.
ix. Translation certificate***and Back Translation certificates.***
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 trialAgreement***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.

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, 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 log of duties.

xxiii. Administrative sanction from the Dean to conduct the research study in this institution and also to send biological samples outside the institution.

xxiv. Cheque Payment of IEC Review charges.

xxv. Letter for waiver of consent whenever applicable

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) vacation***. The datesof the meeting should be fixed by the 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. 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.

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. ***All important discussion /relevant discussion will be minuted.***The decision will be minuted and chairperson's approval taken in writing.

vi. ***All reply to IEC queries unless specifically required to go through the regular meeting (Reply to IEC query letter no. 1) will be examined by minimum 3 members decided by the Chairperson/ Member Secretary.***

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 subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

vi. Management of research related injuries, adverse events.

vii. Compensation provisions.

viii. Justification for placebo in control arm, if any.

ix. Availability of products after the study***(Post trial access of the IP)***, if applicable.

x. Patient information sheet and informed consent form in ***vernacular*** languages***and provisions for taking appropriate informed consent process.***

xi. Protection of privacy and confidentiality.

xii. Involvement of the community, wherever necessary.

xiii. Plans for data analysis and reporting.

xiv. Adherence to all regulatory requirements and applicable guidelines.

xv. ***Qualification and*** Competence of investigators, research and supporting staff.

xvi. Facilities and infrastructure of study sites.

xvii. Criteria for withdrawal of patients, suspending or terminating the study.

xviii. ***Use or disposal of stored or left over 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 left over 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 examined by minimum 3 members decided by the Chairperson/ Member Secretary. All the three members including the member secretary should preferably be present for the meeting to expedite decision making.

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 ***(i.e. if the member is Principal Investigator)*** 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 Principal Investigator in response to queries will be reviewed by the Member Secretary and 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 Secretaryin 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 approvalatleast 2 months 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.***

d. All serious adverse ***events*** during the study should be reported to the IEC within 24 hours and the principal investigatorshould 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 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 and submission of updated data.***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. ***Principal*** investigator ***shall be responsible*** to protect the dignity, rights, safety and well being of all research participants.

k. ***Principal***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 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 events 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***(Appendix XI) of Schedule Y***. This report will be reviewed by the SAE subcommittee members and will be discussed in the next IEC meeting.

iv. In case of Serious Adverse Events occurring in the clinical trial subjects the principal investigator, after due analysis shall forward the SAE report to the licensing authority within 14 calendar days of occurrence of the Serious Adverse Event.

v. In case of Serious Adverse Events occurring to the clinical trial subjects, 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 ***submittedfor IEC approval***.

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

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***.

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 of the informed consent procedure of each trial subject 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 on31st January 2019.

31-01-19.

Dr. J.H.Hotwani,
Member Secretary, IEC.

31.01.2019

Dr.Y.A. Deshmukh,
Chairperson, IEC.