INSTITUTIONAL ETHICS COMMTTEE
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 28th November 2014.

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 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 research proposals submitted to IEC and to be carried out at these institutes.

The member secretary is responsible for implementing this SOP.

3. ROLE OF IEC:

i. IEC will carry out the ethical review of all types of 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 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 9 to 13 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 9 to 13 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 no-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 institute 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 guideline deemed unfit for a member
v. A member can tender resignation from the IEC with proper reasons to do so and shall give at least one month notice. The letter of resignation should be addressed to the Dean.
vi. All members shall maintain absolute confidentiality of all discussions during the meeting.
vii. Conflict of interest should be declared by the members of IEC.
viii. Both new as well as old members should undergo orientation program and training in national and international developments in bioethics.

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. clinicians
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 alternate chairperson can be elected by the members present for the meeting from any of the member from outside the institute who shall conduct the meeting.

8.OFFICES:

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

Mumbai Central, Mumbai – 400 008

Tel. No. 022-23027207 (Direct) or 23027000 ext. 207

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

EmailID: nairethics@gmail.com

A separate telephone and fax machine shall be made available for the quick communication with all concerned.

Supportive office staff will consist of the following

1. One full time clerk cum typist and computer operator
2. One full time servant cum office attendant.
3. One part time servant
4. One or two resident doctors (PG student) registered for M.D. (Pharmacology) shall be posted by rotation in IEC office to assist member secretary.

Additional person of suitable qualification to manage the administrative work of the office and to monitor the progress of various research proposals may be appointed if required.

The member secretary shall be responsible for organizing the meeting, maintaining the records and communicating with all concerned. He shall prepare the minutes of the meetings and get it approved by the Chairperson.

9. INDEPENDENT CONSULTANTS

IEC may call upon subject expert as independent consultants who may provide special review of selected research proposal if need be. These experts may be specialists in 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 but they will not have right to vote which will be made by the members of the IEC.

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 by the head of the department to the IEC. All IEC documents should be submitted in the IEC office.

iv. All the proposals should be received at least 3 weeks before the date of the next IEC meeting.

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

vi. The date of the meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

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

Type of Research Project	Ethics Review Charges (excluding TDS0	Continuation charges beyond one year (Excluding TDS)
Pharmaceuticals company sponsored projects	Rs.50,000/-	Rs.10,000/-
Sponsored projects concerned with diagnostic kits or projects with budget less than 2.5 lakhs	20% of the budget	10% of the budget Or Rs.10,000/- whichever is less.
ICMR and Government Sponsored a)Interventional Project b)Other projects	 10% of the total budget or Rs.50,000/- whichever is less. 5% of the budget or Rs.30,000/- whichever is less	 5% of the budget or Rs.10,000/- whichever is less. 2.5% of the budget or Rs.5,000/- whichever is less.

11. DOCUMENTATIONS

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

i. Application form
ii. Summary sheet
iii. Study protocol
iv. Case Record Form (CRF)
v. Patient information Sheets in suitable languages (English, Marathi and Hindi) as necessary.
vi. Informed Consent Form (ICF) in suitable languages (English, Marathi and Hindi) as necessary.
vii. Assent form when research involves children aged 7 years and above.
viii. Translation certificate if necessary.
ix. Additional documents such as questionnaires, patient diary card, advertisement for recruitment of study participants etc. if required.
x. 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.
xi. Agreement between the investigator and the sponsor (Clinical Trial Agreement).
xii. Source of funding and financial requirements for the project.
xiii. Insurance liability copy and compensation policy for SAE occurring during the study.
xiv. Curriculum Vitae of the investigators and GCP training certificate.
xv. DCGI permission letter if required.
xvi. Undertaking by the investigator.
xvii. CTRI number in case of clinical trial
xviii. Statement of conflict of interest, if any.
xix. Any other information relevant to the study.

12. REVIEW PROCEDURES

i. The meeting of the IEC should be held on scheduled intervals. IEC shall hold regular meeting once every month except during the vacation. The dates of the meeting should be fixed by the secretary in consultation with the chairperson of the committee.

ii. No projects will be received unless and until the necessary IEC review charges has been paid. The study related documents will not be accepted if all the documents does not comply with the check list necessary for review of study protocol. The research proposal should be sent to the members at least 10 days in advance.

iii. Decisions will be taken by consensus after discussions and if needed voting will be taken. In case of a tie chairperson may either cast a deciding vote or postpone the decision to the next meeting.

iv. Researcher will be invited to offer clarifications if need be.

v. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

vi. The decision will be minuted and chairperson's approval taken in writing.

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

v. Management of research related injuries, adverse events.

vi. Compensation provisions.

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

viii. Availability of products after the study, if applicable.

ix. Patient information sheet and informed consent form in local languages.

x. Protection of privacy and confidentiality.

xi. Involvement of the community, wherever necessary.

xii. Plans for data analysis and reporting.

xiii. Adherence to all regulatory requirements and applicable guidelines.

xiv. Competence of investigators, research and supporting staff.

xv. Facilities and infrastructure of study sites.

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

14. EXPEDITED REVIEW

All revised proposal unless specifically required to go through the regular meeting will be examined in meeting of the sub-committee of 3 members to be nominated by the Chairperson. All the three members including the member secretary should be present for the meeting to expedite decision making.

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

Decision taken by the sub-committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the 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 indicated 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 will only offer their opinions.
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 secretary or one or members or the full board in a meeting and a decision will be taken.
vii. Modified proposals may be reviewed by an expedited review through identified members.

a. Approval of a proposal shall be valid for a period of one year. IEC shall charge fees of Rs 10,000 (excluding T.D.S.) per year for the continuation in case of sponsored research.

16. COMMUNICATING THE DECISION

i. Decision will be communicated by the Member Secretary in writing within 10 working days from the date of the meeting.

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

iii. Suggestions for modifications, if any, should be sent by IEC.

iv. Reasons for rejection should be informed to the researchers.

v. The schedule / plan of ongoing review by the IEC shall be communicated to the PI.

vi. 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 must be mentioned.
10. In the case of positive decision, 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 this letter and if the project continues beyond a year, re-approval of EC must be sought.
    c. Any change in the protocol or standard recording documents should be intimated to the EC for information and approval.
    d. All serious and unexpected adverse reactions to the test drug observed during the study should be reported to the EC within 24 hours. and the principal investigator should take appropriate measures to manage the SAE and adverse reactions.

e. The principal investigator has to reply to the IEC queries within a period of 3 months of receiving the IEC query letter.

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 charges. If the project is not initiated within 24 months of intial approval, no further continuation shall be granted and the approval shall lapse.

g. In the case of the injury /disability/ death of a research participant attributable to the test drug in strict adherence to the approved protocol, the responsibility of compensation /treatment will rest on the sponsor of the trial.

h. The principal investigator should intimate to the EC immediately 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 3 months of completion of the project

j. The investigator should take all the necessary care to protect the dignity, rights, safety and well being of all research participants.

k. Investigator must ensure to obtain from Sponsor any new information that may affect the risk/benefit ratio of the study and intimate the same to EC at the earliest. EC 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 review the progress of all the studies for which positive decision has been reached

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 Serious Adverse Events (SAEs) or unexpected adverse drug reactions should be intimated to the IEC within 24 hours of knowing the occurrence. All on site SAEs should be reported in a specified format mentioned in the separate SOP for managing SAEs at this institute.

iv. In case of SAE Serious Adverse Events occurring in the clinical trial subjects the principal investigator, after due analysis shall forward the SAE report to the licensing

authority, Chairman 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 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 sponsored or his representative, whosoever had obtained permission from the licensing authority for conducting the clinical trial, to the Licensing authority with in 30 calendar days of the occurrence of the Serious Adverse Event.

vi. In the case of the injury / disability/ death of a research participant attributable to the test drug in strict adherence to the approved protocol, the responsibility of compensation /treatment will rest on the sponsor of the trial.

vii. Any amendment to the protocol should be resubmitted for renewed 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. Applicant must inform the time of completion of study and must send the summary of the data obtained.

xii. Final report of the study should be sent to the IEC within a period of 3 months of completion.

xiii. Change of investigators / sites should be informed to the IEC

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 EC 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 he Principal Investigator.

The above Standard Operating Procedures (General) Revised version have been reviewed and approved by the IEC in its meeting held on 28th November 2014..

Dr. J.H.Hotwani
Member Secretary
IEC

Dr. Mrs. Hemlata R. Iyer
Chairperson
IEC