1. Preamble

The objective of this document is to contribute to the effective functioning of the Institute Ethics Committee (IEC) at IIT Bombay (IITB), so that a transparent and consistent review mechanism is put in place for proposals submitted to the Committee. This is as prescribed by the Ethical Guidelines for Research on human subjects and biological samples from human subjects.

2. Role of the Institute Ethics Committee

This is as prescribed by the Indian Council of Medical Research (ICMR):

The mandate of the IEC will be to review all types of biomedical / health related research proposals for compliance with the IEC. Also included are proposals involving biological samples, vulnerable population and/or sharing of confidential information involving human subjects, with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants to be conducted by researchers of IITB. The goals of research, however important, shall never be permitted to override the health and well-being of the research subjects.

IEC will ensure that the proposed methodology adheres to the cardinal principles of research ethics viz., Autonomy, Beneficence, Non-malfeasance and Justice, are included in the planning, conduct and reporting of the proposed research.

IEC will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit, and provisions for appropriate compensations wherever required.

IEC will review proposals before start of the study, and after completion of the study through documented procedures. IEC will not review / approve a study retrospectively.

.

3. Composition of IEC

IEC will be multidisciplinary in composition **as per ICMR recommendations**.

The number of persons in the IEC will be in line with the requirements and scope of work. The composition will be as follows:

i. Chairperson – the Chairperson of IEC will be from outside IITB, preferably of a medical background
ii. Legal expert – the legal expert will be preferably from outside IITB
iii. One or more basic scientists – may be from the academic units of IITB.
iv. One or more Clinicians– including the Chief Medical Officer (ex officio), IIT Bombay Hospital
v. One or more Social scientists / philosophers/ ethicists / theologians – may be from the Humanities and Social Sciences department of IITB or other institutes
vi. One or more persons from the local community
vii. Member-Secretary – will be from IRCC, IITB
viii. Safety Officer, IITB (ex-officio)

If required, subject experts may be invited by the Member-Secretary or Members or Chairperson, to seek their views.

4. Authority under which IEC is constituted

The Director of IITB will constitute the IEC.

5. Membership requirements

i. The members will have a term of three years which can be renewed at the end of the term.
ii. A member can be replaced in the event of his/her long-term non-availability. A member can tender resignation from the committee stating the reasons to do so.
iii. All members must maintain absolute confidentiality of the deliberations of the .
iv. All members must declare conflict of interest, if any.

6. Quorum requirements

The quorum for the review of a proposal should have at least one representative from the following spheres:

- Legal expert
- Clinician
- Basic Scientist
- Social Scientist

- Community Representative

Every proposal received for review by IEC will be discussed in at least one meeting, and no decision will be taken for any proposal that has not been reviewed in a meeting. Proposal reviewed in expedited mode ("Expedited Review") may not be discussed in full board meetings. However, the committee will be kept informed of such a proposal and its status.

7. Offices

The Chairperson will conduct all meetings of the IEC. If the Chairperson is not available for reasons beyond control, the Chairperson may nominate a co-chair for the meeting.

The Member Secretary will be responsible for organizing meetings, maintaining records and communicating with all concerned. The Member Secretary will prepare the minutes of meetings and circulate the comments to PIs post the meeting.

8. Application Procedures

i. A calendar of proposal submission dates and corresponding IEC meeting dates will be circulated in advance, via electronic mail to IITB faculty.
ii. All proposals should be submitted in prescribed formats, available on DRONA (http://drona.ircc.iitb.ac.in). Formats may be updated from time to time by the member secretary
iii. The Principal Investigator (PI) must submit proposals by the given due dates.
iv. Each proposal will receive a unique proposal number with the format IITB-IEC/YYYY/Proposal No. where YYYY is the calendar year in which the proposal is reviewed and proposal no. will be allotted in the order of review by the IEC
v. The proposal signed by the PI, containing all the relevant information including the enclosures such as the Informed Consent Forms (ICFs) and their translations must be submitted as a single pdf file, via electronic mail to the Member Secretary.
vi. Member Secretary will forward the proposals by electronic mail to the IEC members for review and comments.
vii. Members will opine on the proposal and may seek clarifications as and when necessary.
viii. Comments by members will be compiled by the Member Secretary and forwarded to the PI in advance so that PIs can come prepared with responses for clarifications sought.
ix. PI shall make the presentation for the IEC meeting and may bring along co-PIs only.
x. Every PI will present the proposal, followed by discussions.

xi. IEC members will have closed door discussions on the proposal, recommendation and /or decision.
xii. Up to four proposals may be taken up during any IEC meeting. This number may be increased if the proposals do not need much discussion by the IEC.
xiii. The recommendations and decisions of the IEC on the proposal will be communicated by electronic mail, to the PI by the Member Secretary.
xiv. If revision is to be made, the revised document should be submitted to the Member Secretary. The revised version will be forwarded to members by electronic mail.

9. Documentation (as per ICMR guidelines)

All research proposals must be submitted with the following details:

i. Name of the applicant with designation. Only IITB staffs ~~(~~who are permitted to be PIs as per the norms of IITB~~)~~ can be applicants.
ii. Details of the Site/ Institute/ Hospital/ Field area where research will be conducted.
iii. Protocol of the proposed research with complete details on:
    a. scientific rationale (including results of previous animal and human studies)
    b. hypothesis
    c. study design
    d. risks involved in the design of the study
    e. statistical basis for the structure of the investigation
    f. potentially harmful effects that can be adequately detected, prevented, or treated
iv. Risks involved in the study design must be categorized by the PI as one of the following:~~.~~
    a. Less than minimal risk:
    Research in which there is no known physical, emotional, psychological or economic risk.
    b. Minimal risk:
    Probability and magnitude of harm or discomfort anticipated in the research are in and of themselves not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
    c. Greater than minimal risk:
    Research procedures that may include risk beyond that ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, biologics or medical devices, stressful psychological testing, use of special populations).
v. Ethical issues in the study and plans to address these issues.
vi. Relevant enclosures like Informed Consent Form, its translation in local languages, questionnaires, etc.

vii. For any trial of drug / device, all relevant pre-clinical animal data and clinical trial data from other centres within the country or from other countries, if available.
viii. CVs of all the investigators with relevant publications during the last five years.
ix. Any requirements of regulatory clearances.
x. Source of funding and financial requirements for the project.
xi. Other financial issues including those related to insurance.
xii. An agreement to report only Serious Adverse Events (SAE) to IEC.
xiii. Statement of conflicts of interest, if any.
xiv. Agreement to comply with the relevant national and applicable international guidelines.
xv. A statement describing any
    a. compensation for study participation (including expenses and access to medical care) to be given to research participants;
    b. a description of the arrangements for indemnity, if applicable (in study-related injuries);
    c. a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g.,those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
xvi. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
xvii. Any other information relevant to the study
xviii. Proposals incomplete in any of the above details shall not be taken up for review by IEC, until all the information is provided.

10. Review procedures (as per ICMR guidelines)

All research proposals shall be reviewed as follows:

i. The meeting of the IEC will be held on scheduled dates, as given in the calendar of IEC meeting dates, shared with PIs in advance via electronic mail to faculty-of IITB.
ii. Proposals must be submitted by submission due dates and will be taken up for review on a first-come-first-served by the date of submission. Proposals received after the due date will be taken up for review in the next IEC meeting, as per the calendar.
iii. One to two committee members (primary reviewers) will review and submit their comments on the proposal prior to the meeting. These comments and a list of clarifications will be forwarded to the PI prior to the meeting. PIs must be present in the IEC meeting in which their proposal is to be reviewed.
iv. Decisions will be taken after due deliberations and discussions.

v. PIs will be invited to provide clarifications if needed.
vi. Independent consultants/Experts may be invited to offer their opinion on specific research proposals if needed.
vii. Decisions will be minuted, confirmed electronically by members and Chairperson, and formally confirmed at the next meeting.

11. Elements of review

As per ICMR guidelines, all research proposals shall be reviewed for the following:

i. Scientific rationale, hypothesis, study design and conduct of the study.
ii. Approval of appropriate scientific review committees, if available.
iii. Examination of predictable risks/harms.
iv. Examination of potential benefits.
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, etc. when applicable.
vii. Compensation provisions.
viii. Participant information sheet and ICF in local language(s).
ix. Protection of privacy and confidentiality.
x. Plans for data analysis and reporting.
xi. Adherence to all regulatory requirements and guidelines
xii. Competence of the investigators
xiii. Facilities and infrastructure of study sites, as applicable
xiv. Criteria for withdrawal of patients, suspending or terminating the study

12. Expedited review

Expedited review (not involving full board meeting) can be undertaken under the following circumstances:

i. When the proposal involves no more than minimal risk or less than minimal risk, the proposal will be reviewed by some members (1-2 members keeping the Chairperson informed). A justification for expedited review should be provided by the PI in this case. The reviewer(s) may decide to review and approve the proposal in expedited mode or move the proposal to full board review based on the contents of the proposal.
ii. For proposals approved in-principle and pending minor modifications in the proposal (conditional decisions),
    a. recommendations of the IEC will be communicated by the Member Secretary to PI via electronic mail.
    b. the revised document should be submitted electronically to the Member Secretary.
    c. the revised document will be forwarded via electronic mail to concerned members by the Member Secretary.

iii. members will send in their comments on the revised document and consent for approval of the study as applicable via electronic mail. No expedited review is allowed for a proposal that is specifically required to be resubmitted to the committee for a subsequent meeting.

13. Decision-making (as per ICMR guidelines)

The decision-making process followed shall be as follows:

i. IEC members will discuss various issues before arriving at a consensus decision.
ii. Members with potential conflicts of interest will recuse from decision making. Such conflicts of interest 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 members must make the decision. The expert consultants shall only offer their opinions.
v. Decision may be to approve, revise or reject a proposal. Specific suggestions for modifications and reasons for rejection will be given.
vi. In cases of conditional decisions, clear suggestions for revision will be specified.
vii. The procedure for having the application re-reviewed will be specified as either expedited review or resubmission to a subsequent meeting. The proposal for re-review must be submitted within 180 days of receipt of IEC recommendations.
viii. Any appeal on the IEC's decision may be made first to the IEC Chairperson, The Chairperson can decide to re-review, uphold or reverse the recommendations taking PI's feedback into consideration.
ix. Appeal can be made to the Director of IIT Bombay if a proposal is rejected by IEC. Director may seek clarifications from the Member Secretary and decide or further appoint a committee for deciding on the proposal. The decision of the committee constituted by the Director shall be final in such cases.
x. PIs should note that IITB-IEC can provide IEC approval for research projects only. PIs should approach DCGI registered ethics committees for IEC clearance of regulatory trials. In the latter case, IITB IEC should receive a copy of the IEC approval letter.

14. Communicating the decision

i. The Member Secretary will send recommendations for revision and re-review / any other decision to the PI via electronic mail.
ii. Reasons for rejection will be informed to the PI.
iii. Based on the consent of members to approve a proposal, either during the IEC meeting or on perusal of a revised document received subsequent to the IEC meeting, the approval letter shall be prepared by the Member Secretary.
iv. The approval letter will be signed by the Member Secretary on behalf of Chairperson of the IEC. The approval letter will be as per Annexure 1.

v. Both the original approval letter and its soft copy will be shared with the PI.

15. Follow up procedures

i. The PI must monitor the study.
ii. All SAEs and the interventions undertaken should be intimated.
iii. Protocol deviation, if any, should be informed with adequate justifications, prior to the deviation and the amended protocol should be resubmitted to IEC for renewed approval.
iv. Any new information related to the study should be communicated.
v. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
vi. Change of investigators / sites should be informed.
vii. A final report must be submitted at the end of study.

16. Record keeping and Archiving

i. Curriculum Vitae (CV) of all members of IEC.
ii. Copies of all study protocols with enclosed documents, progress reports and SAEs.
iii. Minutes of all meetings.
iv. Copy of existing relevant national and international guidelines on research ethics and laws.
v. Copy of all correspondence with members, researchers and other regulatory bodies.
vi. Final report of the approved projects.
vii. The soft copy documents will be archived at IRCC for a period of five years after the study is approved.

17. Updating IEC members

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

Members are encouraged to attend national and international training programs in research ethics for maintaining quality of review process and be aware of the latest developments in this area.

18. Reference

Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research, Indian Council of Medical Research

19. Nomenclature

CV: Curriculum Vitae
ICF: Informed Consent forms
ICMR: Indian Council of Medical Research

IEC: Institute Ethics Committee
R&D: Research and Development
IITB: IIT Bombay
PI: Principal Investigator
SAE: Serious Adverse Events
SOP: Standard Operating Procedures

REVISION HISTORY

S. No.	Revision Date	Revision Number	Revision History
1.	Jan 2017	V01	Refer Revision History v01_final