Regional Institute of Ophthalmology

Medical College & Hospital
Kolkata-700 073

Standard Operating Procedures (SOP)

Institutional Ethics Committee

Regional Institute of Ophthalmology
88, College Street,

Kolkata –700073; West Bengal,India

Version: 3.1

Date: 18/JUNE/2022

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	Designation	**Chairperson**	**Date**	09/07/22

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1. Objective of SOP:

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (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 committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR, ICH GCP, Indian GCP and applicable regulatory requirements.

2. General principles in biomedical research involving human subjects:

The committee will ensure a strict concordance with the statements of General principles on Research using Human Subjects in Biomedical Research as well as the Statement of Specific Principles on Research using Human subjects in specific areas of biomedical Research, as laid down by Indian Council of Medical Research (ICMR).

The general statement includes:

- The Purpose of the research should be directed towards the increase in knowledge about human beings
- Research is conducted under conditions that no one person/persons becomes a mere means for the betterment of other.
- Research is subjected to a regime of Evaluation at all stages on proposal, i.e. design, experimentation, statistical validity, declaration and use of results thereafter.

To ensure that the research protocols that are carried out at **Regional Institute of Ophthalmology, Kolkata**are in accordance to the guidelines laid down by Indian Council of Medical Research (ICMR), Indian GCP, ICH GCP, Schedule Y &New Drugs and Clinical Trials Rules 2019, the following criteria, but not limited to these only, must be met:

- Do not compromise the safety of the subject.
- Study procedures to be conducted under the supervision of medical persons with the required expertise

- Include solely patients who have given voluntary and informed, consent to participate in the clinical study.
- Any research using the human beings as subjects of medical or scientific research or experimentation shall bear in mind the following principles.

i. **Principles of essentiality** whereby, the research entailing the use of human subjects is considered to be absolutely essential after a due consideration of all alternatives.

ii. **Principles of voluntariness, informed consent and community agreement** whereby, research subjects are fully apprised of research subject and others.

iii. **Principle of non-exploitation**, whereby, as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects kept fully apprised of all the dangers arising in and out of the research.

iv. **Principles of privacy and confidentiality** whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential.

v. **Principles of precaution and risk minimization** whereby, due care and caution is taken at all stages of the research and experiment.

vi. **Principles of professional competence** whereby, the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality.

vii. **Principles of accountability and transparency** whereby, the research or experiment will be conducted in a fair, honest, impartial and transparent manner after a full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research.

viii. **Principles of the maximization of the public interest and of distributive justice** whereby, the research or experiment and its subsequent appreciative use are conducted and used to benefit all human kind.

ix. **Principle of institutional arrangements** whereby, there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to me made in respect of the research and its subsequently use or application are duly made in a benefit and transparent manner.

x. **Principle of public domain** whereby, the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain.

xi. **Principle of totality of responsibility** whereby, the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment.

xii. **Principle of compliance** whereby, there is a general and positive duty on all persons conducting, associated or connected with any research entailing the use of a human subject.

3. Role of Institutional Ethics Committee (IEC):

IEC will review and approve 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. The goal of research, however important will never be permitted to override the health and well-being of the research subjects. The IEC will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-malfeasance and justice are taken care of in the planning, conduct and reporting of the proposed research. For this purpose, IEC will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefits and provision for appropriate compensations wherever required.

It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures. The committee will also examine compliance with all applicable regulatory requirements, applicable guidelines and laws.

4. Authority under which Institutional Ethics Committee (IEC) is constituted:

The Institutional Ethics Committee is constituted by the authority vested in the **Director of Regional Institute of Ophthalmology, Kolkata**. The Institutional Ethics Committee has been constituted under the guidelines of ICMR, Schedule Y, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP)&New Drugs and Clinical Trials Rules 2019.

Name: Institutional Ethics Committee, Regional Institute of Ophthalmology

5. Composition of the IEC:

The Institutional Ethics Committee of the **Regional Institute of Ophthalmology** is multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of the IEC. The Chairperson of the Committee is from outside the Institution. This is to maintain the independence of the Committee. The Member Secretary is from the Institution and will be responsible for day to day activities of the IEC. Other members are mix of medical / non-medical, scientific and non-scientific background, including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. 1-2 basic medical scientists
3. 1-2 clinicians
4. One legal expert
5. One social scientist / representative of non-governmental voluntary agency

6. One lay person from the community
7. Member-Secretary

The IEC have adequate representation of age, gender, community etc. in the committee to safeguard the interest and welfare of all sections of the community/society. All the IEC members are aware of the local, social and cultural norms to facilitate the competent review of the proposals and also to protect the rights, safety and well-being of the human subjects participating in the biomedical research.

If required, IEC may invite subject experts to offer their views, for example for drug trials a pharmacologist; preferably a clinical pharmacologist may be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the committee.

All the members will be appointed by the**Director**of **Regional Institute of Ophthalmology, Kolkata** with appropriate documentation of their appointment and acceptance. The appointment will be based on their competencies and integrity.

6. Membership requirement and recruitment of members:

- The members for IEC will be recruited by the Director of **Regional Institute of Ophthalmology** initially for a period of 5 years. A copy of letter of appointment and acceptance, member profile (CV), the confidentiality agreement & disclosure of conflict of interest agreement duly signed by all the members will be kept as IEC records.
- At the end of 5 years, as the case may be, the committee will be reconstituted, and 25% of the members will be replaced with a formal documentation of reconstitution and replacement.
- A member can be replaced in the event of death or long term non-availability (i.e. absence of a member in three consecutive IEC meetings) or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

- A member can tender resignation from the committee with proper reasons to do so.
- All IEC members should maintain absolute confidentiality of all discussions during the meeting and must sign a confidentiality form.
- Prior to involvement in IEC meetings, all members must declare their conflict of interest. If prior to any meeting a member deems that he/she has a conflict of interest in a study to be discussed, then he/she must immediately disclose the conflict of interest and must not participate in the deliberation of the IEC.
- All members must be trained prior to their involvement in IEC meetings.
- IEC members should be selected in their personal capabilities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC's work.

7. Quorum requirement:

According to schedule Y of Drugs and Cosmetics Act, 1940, minimum of 5 members are required to compose a quorum. All decisions must be taken in meetings and not by circulation of project proposals. Minutes of Meeting along with the list of members present during the meeting must be maintained.

i. Basic Medical Scientist
ii. Clinician
iii. Legal Expert
iv. Social Scientist / Representative of NGO / Ethicist / Theologian.
v. Lay person from community

8. Responsibilities of IEC Members:

i. Review the protocols
ii. Attend the EC meetings (6 or more per year)
iii. Opine on the new project provided

iv. Monitoring of approved projects, with special reference to Adverse events/SAE
v. Survey of execution of the projects, as and when required
vi. Provide inputs to the Data Safety Monitoring Committee
vii. Maintain confidentiality

9. Resignation / replacement /termination / disqualification procedure:

The members who have resigned may be replaced at the discretion of the appointing authority for the same. EC members who decide to resign must provide at least 30 calendar days' notice prior to the next scheduled meeting. Appointment may be made in the consultation with Member Secretary and Chairperson

A member may be relieved or terminated of his/her membership in case of:

i. Long term non-availability (i.e. absence of a member in three consecutive IEC meetings)
ii. For any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
iii. Inability to participate in the IEC meetings on any grounds
iv. Relocation to another city or any such matter, from where member cannot participate in the IEC deliberations.

10. IEC membership list:

Table 1: IEC membership list with name, qualification, designation & role in IEC, specialty, contact details, gender and affiliation:

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number,	Designation/ Role of member in Ethics	Affiliation of member with institute that has constituted the Ethics

				e-mail I.D, and mailing address	Committee	Committee
1	**Dr. Santanu Sen**	MBBS, D.O, M.S, (Ophthalmology), PhD (Ophthalmology)	Visiting Consultant, Indian Statistical Institute, Kolkata)	9433103348 drsantanusen@gmail.com	Chairman	EC Chairperson Outside the Institute
2	**Dr. Purban Ganguly**	MBBS, M.S (Ophthalmology)	RMO cum Clinical Tutor, Regional Institute of Ophthalmology, 88, College Street, Kolkata - 700073	9830558823 Drpurban85@gmail.com	Member-Secretary	EC Member Secretary, RMO cum Clinical Tutor, Regional Institute of Ophthalmology
3	**Dr. Lakshmi KantaMondal**	MBBS, M.S, (Ophthalmology), PhD (Ophthalmology)	Professor, Regional Institute of Ophthalmology, 88, College Street, Kolkata - 700073	9830830216 Lakshmi.mondal62@gmail.com	Clinician	EC Member, Clinician, Professor, Regional Institute of Ophthalmology
4	**Dr. Manab Nandi**	MBBS, MD (Pharmacology) M.Phil (Regenerative Medicine)	Associate Professor, Medical College, Kolkata, 88, College Street, Kolkata - 700073	9830835743 manabn@gmail.com	Basic Medical Scientist	EC Member, Basic Medical Scientist, (Outside the Institute)

5	**Mr. Rajesh Arora**	B.Sc	Member of SwasthyaSankalp, 12, Kyd Street, Kolkata	9331016096 rajesharora@gmail.com	Social Worker	EC Member, Social Worker, (Outside the Institute)
6	**MandabiBhattacharrya**	M.Sc (Psychology)	Psychologist, baul Mon, 34, Jadavpur, Central Rd, Golf Green, Kolkata, West Bengal - 700032	9475218866 Mandabi.ju@gmail.com	Scientific member	EC Member, Scientific member, (Outside the Institute)
7	**Mr. Rakesh Arora**	B.Com	Businessman, Blue Cross Surgical Co., Kolkata - 700073	2234-8067/2221-5273	Lay Person	EC Member, Lay Person, (Outside the Institute)
8	**Suparna Ray**	B.Sc, B.A.L.L.B	Advocate, Calcutta High Court	9831105688 Chatterjesuparna878@gmail.com	Legal person	EC Member, Legal Person, (Outside the Institute)

11. Conflict of interest:

All IEC, including the Chairperson, are subject to the Policy on Conflicts of Interest approved by the Director, as amended by the Director, from time to time. In the event that a matter arises in which an Ethics Committee member is implicated, the Ethics Committee shall meet without the presence of the implicated Ethics Committee member.

Please refer to Annexure 4 'Confidentiality and Conflict of interest form for IEC members"

12. Terms of reference:

The terms of references for IEC includes description on composition of IEC, terms of appointment of members with reference to the duration of the term, quorum requirement,

the policy for removal, replacement, resignation procedure, frequency of meetings, and payment of processing fee to the IEC for review, honorarium / consultancy to the members / invited experts etc. as given in the SOP.

The SOPs will be revised periodically (i.e. within every two years) or based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members (25%) could be changed every three years. It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed (i.e. three consecutive times) by a member due to illness or other unforeseen circumstances.

13. Training:

All IEC members will be trained on ethical principles, good clinical practice and applicable regulations prior to involvement in IEC meetings. The IEC members will be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body (ies), so that they become aware of their role and responsibilities. . Any change in the regulatory requirements will be brought to their attention. All IEC members must be aware of local, social and cultural norms as this is the most important social control mechanism.

14. The work procedure of the IEC is as follows:

1. IEC SOP is to be written in Times New Roman font with font size 12. The Appendices may have smaller font size to adjust as per the page requirement or size. The SOP will be distributed in controlled form to all the members and other stakeholders. The SOP will be revised within every two years, but if the requirements change it can be revised intermittently. The SOP version or date will be changed only if the SOP is revised. If

the appendices are modified or changed intermittently the SOP need not to be revised. The new appendices may be enclosed along with the SOP to address change or modification in the enclosed appendices.

2. The chairperson will conduct all meetings of the IEC. If for any reasons beyond control, the chairperson is not available, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting.
3. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by Chairperson before communicating to the researchers.
4. Ethics Committee will meet as and when required.
5. Applicant must submit the proposal 21 days in advance of the scheduled IEC meetings.
6. Proposal can be accepted within 7 days of prior case to case basis based on number of proposals, importance of the projects proposed by the Investigator.
7. The IEC member (or Designee) will acknowledge the receipt of the package by signing and dating the acknowledgment copy of the application letter or covering letter. If available, the member (or designee) will stamp the letter with IEC stamp.
8. On receipt of proposal, the documents will be circulated to all the IEC members well in 5 to 7 days advance of the meeting, for detailed review. While reviewing the proposal following criteria should be considered:
   - Minimize risk to the participants
   - Risks must be reasonable in relation to the anticipated benefits
   - Participants are selected equitably
   - Informed consent is adequate, easy to understand and properly documented
   - The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate
   - There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data where appropriate
   - Appropriate safeguards are included to protect vulnerable participants

9. During each meeting limited number of protocols will be discussed (i.e. as decided and communicated by Ethics Committee) keeping in view that all parameters required for competent review are discussed and consensus drawn
10. Quorum of 5 members, as given in the SOP, is required to conduct the IEC meeting. If a member is unable to attend a meeting, his/her opinion on the project MUST be submitted in writing to the Chairperson of the committee, before the date of the meeting for a decision. The members, who are unable to attend a meeting, will not be allowed to vote. But their feedback or suggestions on the proposal may be discussed during the meeting to maintain the multi-sectorial and competent review of the proposal.
11. For expedited review the IEC will meet earlier as is required. Requirement of quorum is similar to that explained above
12. The final decision of the IEC will be in from of any one of the categories given below:
    a. Approval
    b. Disapproval
    c. Modification before Approval
    d. Discontinuation of previously approved project
13. The IEC decisions will be communicated in writing under the signature of the IEC member secretary
14. In case of a positive decision a statement of the responsibilities of the applicant will be communicated. The IEC expects that, the researchers keep the committee informed of, but not limiting to the following:
    - All cases of protocol amendments should be submitted for IEC review and approval before implementation
    - All cases of amendments to the Informed Consent Form and Patient Information Sheet must be submitted to IEC for review and approval before implementation.
    - All cases of amendments to recruitment material
    - Serious and unexpected adverse events related to the conduct of the study
    - Protocol deviation, if any should be informed with adequate justification

- Any new information that may affect the risk/benefit ratio of the study
- Annual progress report (the clock for the same starts from the date of receipt of IEC approval for the study)
- Final report to be submitted at the end of the study
- Premature termination of the study should be notified with reasons along with summary of the data obtained so far
- Site close out to be notified along with the final status report including the details of subjects, IP and documentation
- All administrative changes, which has study implications must be notified to IEC

15. In case of a conditional decision i.e. where ethics clearance is subject to condition i.e. Modification of study documents or requirement of additional documents, the IEC will communicate to the researcher or Investigator the stipulated requirement, including suggestions for revision and the procedure for re-reviewing the application. Any time limit imposed for reply will also be stated.
16. In case of negative decision a clear statement of the reason(s) for the negative decision will be communicated to the researcher or Investigator including whether it may be submitted as new proposal with appropriate changes. The right to appeal and procedure for re-review (if any) will also be communicated.
17. With regard to approval of amendments: should an amendment to a study-related document be administrative in nature and does not involve any change which may jeopardize the subject or the study, then it may be approved by EC in an expedited manner or as an amendment. But the decision to consider the amendment as minor or major lies fully with the IEC. If an amendment is considered major it will be approved during a full meeting involving the full quorum as stated in the Schedule Y.
18. Reported Indian SAE's will be discussed during the IEC meetings to decide on the quantum of compensation and causality of the event.
19. An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ration

20. The discontinuation of a trial may be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
21. IEC allows investigators to present and defend the proposals during the IEC meetings. The Investigator may also be called to present if a clarification is sought on certain issues in the applications
22. IEC may seek help from the outside experts (form within or outside **Regional Institute of Ophthalmology, Kolkata**), if required. 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 do not take part in the decision making process which will be made by members of the IEC
23. Minutes of meetings will be documented and maintained for every meeting conducted by IEC
24. IEC decision will be communicated within 6weeks of the submission for protocols requiring review by the IEC members
25. IEC decision to be completed within 45 days from submission for expedited protocols or amendments
26. All proposals are to be submitted in the prescribed IEC application form
27. Seven hard copies of the proposal along with a soft copy need to be submitted to IEC for competent review
28. The date of IEC meetings will be communicated to researchers or investigators. If there is any change in the schedule it will be communicated well in advance.

15. Types of clinical research projects reviewed by the committee:

- Observational studies
- Record reviews and historical studies
- Surveys, Questionnaires and Interviews
- Epidemiological studies

- Prospective studies either with or without any intervention
- Company sponsored drug trials
- Studies evaluating new devices and implants

16. List of documents reviewed for each clinical trial project:

1. IEC application form
2. Protocol or protocol amendments
3. Investigator brochure or amendments
4. English language informed consent form, translations and its back translations
5. Translation and back translation certificates
6. Any recruitment or retention material or any other advertisement. Their translations and back translations along with certificates, if applicable
7. Insurance policy
8. Updated CVs of the Investigators along with medical registration certificates
9. GCP training certificates of the Investigators
10. Form FDA 1572
11. Undertaking from investigators
12. Copy of Clinical Trial Agreement (CTA)
13. DCGI clearance/approval, if applicable. If approval is awaited mention in application letter and submit the DCGI submission letter
14. CTRI registration number
15. IEC approvals from other investigative site(s), if applicable
16. Other relevant regulatory approvals, if applicable
17. Financial Disclosure Form (FDF) form all investigators
18. Case Report Form (CRFs), subject diary, questionnaires, follow-up cards etc. If translations and back translations to be used then those along with certificates also need to be submitted.

19. Source templates provided by Sponsor. If it is site specific template printed on letter head it must only be notified to IEC for review. Site specific template does not require IEC approval.
20. Any Other relevant documents required for the study

17. Serious adverse events:

Serious adverse events (SAE) will be reviewed in IEC meetings. Opinions from specialists in the particular area, who don't have any conflict of interest, may be taken, if required. In cases of significant SAEs, Principal Investigator of the study will be asked to justify the continuation of the study.

Any SAE, including laboratory test abnormalities, clinical trial related injury or death, regardless of causal relationship, must be immediately reported to the Institutional Ethics Committee Chairman, Sponsor and RA (DCGI) within **24 hours**.

Reporting of fatal SAEs

Investigator to report fatal SAE within **24 hours** of becoming aware [as per APPENDIX XI and XII of Schedule Y and Table 5 of New Drugs and Clinical Trials Rules 2019] to

- Sponsor/Contract Research Organization (CRO),
- Chairman of Ethics Committee
- Drugs Controller General of India (DCGI)

Investigator to submit the analysis report (causality assessment) within **14 Calendar days** of becoming aware of the event to [as per APPENDIX XI & XII of Schedule Y and Table 5 of New Drugs and Clinical Trials Rules 2019].

- Sponsor/CRO (if applicable)
- Chairman of Ethics Committee

- Head of Institute
- DCGI
- Chairman of Expert Committee

In case of serious adverse event of death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the:

- Chairman of Expert Committee
- Licensing Authority (DCGI)

The report need to be submitted within 21 calendar days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA/Expert Committee.

Reporting of Non-Fatal SAEs

Investigator to report non-fatal SAE within **24 hours** of becoming aware [as per APPENDIX XI and XII of Schedule Y and Table 5 of New Drugs and Clinical Trials Rules 2019] to

- Sponsor/CRO
- Chairman of Ethics Committee
- DCGI

Investigator/Sponsor to submit the analysis report (causality assessment) within **14 Calendar days** of becoming aware of the event to [as per APPENDIX XI & XII of Schedule Y and Table 5 of New Drugs and Clinical Trials Rules 2019]:

- Chairman of Ethics Committee
- Head of Institute
- DCGI

In case of serious adverse event other than death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to:

- Licensing Authority (DCGI)

The report needs to be submitted within 21 calendar days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA.

- **SAE Reporting on Sugam Portal:**

As per the new mandate on SAE reporting for online and offline application IEC follows:
User Manual for SAE reporting (Serious Adverse Event) On SUGAM portal
Version 1.0 enclosed herewith the SOP.

18. Vulnerable groups:

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- Research on genetics should not lead to racial inequalities;
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
- Rights and welfare of mentally challenged and mentally differently abled persons who are incapable of giving informed consent or those with behavioral disorders must be protected.

- Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented
- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, Children, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

19. Record keeping:

All documentation and communication of an Ethics Committee are to be dated, filed and preserved according to the standard operating procedures. It is the responsibility of IEC staff to ensure that all study files are prepared, maintained, and kept securely for a period of not less than five years (both in soft and hard copy) form the date of study completion or termination. . Approved protocols are assigned unique identifier that ensures confidentiality and facilitates retrieval at any time. Strict confidentiality must be maintained during access and retrieval procedures. Records should be maintained for the following namely:

- The constitution and composition of the IEC
- The curriculum vitae of all IEC members;
- Standard operating procedures followed by the IEC
- National and international guidelines;
- Copies of the protocol, data collection formats, CRFs, investigational brochures etc. submitted for review;
- All correspondence with IEC members and investigators regarding application, decision and follow up;
- Agenda of all IEC meetings;
- Minutes of all IEC meetings with signature of the Chairperson;

- Copies of decisions communicated to the applicants;
- Record of all notification issued for premature termination of a study with a summary of the reasons;
- Final report of the study including microfilms, CDs and Video-recordings.

All closed study files will be separately archived. After completion of archival period the closed files will be shredded and disposed of. A log book of disposed documents will be maintained.

20. Management of regulatory inspection:

The regulatory inspection of the IEC can be conducted with or without prior notification by the regulatory agency. Foreseeing the regulatory inspection the IEC will take all the measures required to ensure that the trials are conducted strictly in accordance with the clinical trial regulations and guidelines.

Ethics committee shall remain open for inspection by the inspectors or officials of the Central Drugs Standard Control Organization (CDSCO). The IEC shall allow inspectors or officials of the CDSCO to enter its premises to inspect any record, data, or document related to clinical trials approved by the IEC and shall provide adequate replies to queries/observations (if any) raised by such inspectors or officials of the CDSCO in relation to the conduct of the clinical trial.

Preparation for the Regulatory Inspection:

i. IEC will be registered under the Licensing Authority. The renewal of registration will be done three months prior to the expiry of registration. For this IEC will keep a track of the registration approval date
ii. IEC will be constituted as per the ICMR Guidelines & Schedule Y
iii. IEC will ensure that the right, safety and well-being of the subjects participating in the biomedical research is always protected
iv. IEC will review all study protocols considering the following criteria:
    - Minimize risk to the participant

- Risks must be reasonable in relation to anticipated benefits
- Participants are selected equitably
- Informed consent is adequate, easy to understand and properly documented
- The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants, where appropriate
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate
- Appropriate safeguard are included to protect vulnerable population

v. IEC will maintain all appropriate records to substantiate proper functioning of the Ethics Committee deliverables

vi. If the Inspection is conducted with prior notice, all the members of the IEC will be made aware of the Inspection

During Inspection:

- During the Inspection the delegated personnel from IEC will be present to face the Inspection
- He/she will provide the inspectors with requested records/documents
- If any questions are raised by the Inspectors, the delegated personnel will answer all the questions to the point and with facts/evidence.

After Inspection:

- On receipt of the query letter, if applicable, the IEC will ensure that all queries are addressed within the stipulated timelines
- If required the corrective actions will be implemented

21. Conducting audits of the investigative sites: It is the responsibility of the IEC members to perform on-site inspection of selected studies of relevant projects it has

approved to ensure the rights and safety of the research participants. The members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit. Committee may have assigned the duty to someone qualified by education and training. Record for the same will be kept with the EC Member secretary. A complete report of the findings is sent to the Chairperson within 14 days of the audit and presented during the Full Board Meeting. The IEC recommendations are communicated to the PI within 14 days of the meeting Frequency of the auditing of any protocol approved by the IEC is decided on the interim study reports submitted to the IEC.

22. Expedited review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the IEC or designated member of the committee may do expedited review only if the protocol involves:

- Minor deviations from originally approved research during the period of approval (usually of one year duration)
- Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis
- Research activities that involve only procedures listed in one or more of the following categories :

  Clinical studies of drugs and medical devices only when -

  - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population

    or
  - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
- When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study

a) **Research on interventions in emergency situation**

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients –

I. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

II. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

III. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

IV. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b) **Research on disaster management**

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society,

community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

I. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

II. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

III. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

IV. Protection must be ensured so that only minimal additional risk is imposed.

V. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster-affected population and a prior agreement should be reached on this, whenever possible, between the community and the researcher.

VI. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

VII. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

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APPENDIX

Appendix-I
IEC APPLICATION FORM

Instruction: Submit 07 copies of the research documents along with the application form or covering letter mentioning all the documents needs to review and approved. One soft copy on CD also needs to be submitted to the Member Secretary of **Institutional Ethics Committee, Regional Institute of Ophthalmology.**

No research project shall be/can be started unless ethics clearance/approval is obtained.

This form must not be used for submitting amendments. The amendments can be submitted along with the covering letter.

1. Protocol Title:		
Protocol No.:		**Total Study Participants:**

2. Study Type: Tick the applicable:				
Survey	☐	**Retrospective**	☐	**Prospective**
Social	☐	**Behavioral Research**	☐	**Community Based**
Observational	☐	**Epidemiology**	☐	**Interventional**
Clinical Trial	☐	**Genetic Study**	☐	**Other:** _____ _____

3.Phase of Clinical Trial:						
Phase I	☐	**Phase II**	☐	**Phase III**	☐	**Phase IV**

4. Study Investigators Details:	
Name of Investigators/Co-Investigator	**Designation**

Note: If more investigators give details under the extra comment section.

5. Study Objectives:

5. Study Objectives:

6. Justification for the Conduct of this Study:

7. Methodology:	
Inclusion Criteria	
Exclusion Criteria	

7. Methodology:	
Control(s)	
Study Design	
Dosage of Drug	
Duration of Treatment	
Investigations Specifically related to Project	
Permission to use copyrighted Questionnaire/Performa	

7. Methodology:	
Other	

8.Regulatory Permission:			
Permission from DCGI	**Required**	☐	**Not Required**
	Received	☐	**Applied when**

9. Safety:	
Safety measures for proposed interventions	
Results of relevant laboratory tests	
Results of studies in humans	

9. Safety:	

10. Plans to Withdraw Standard Therapy During the Conduct of Research:	
Yes ☐ No ☐	**Remarks:**

11. Provision of Coverage for Medical Risk(s) During the Study Period:

12. How you will maintain confidentiality of subject?

13. Total Budget (approx. in Rs). Who will bear the cost of investigation/implants drugs/contracts?

14. Participant Information Sheet and Informed Consent Form		
English	☐ Yes ☐ No	Version/Date
Translated	☐ Yes ☐ No	Languages
Back Translated	☐ Yes ☐ No	

15. Conflict of Interest for any other Investigator(s), If yes please explain in brief:		
Sl. No.	Name of Investigator	Brief Description
1.		
2.		
3.		
4.		
5.		

16. Whether any work on this project has started or not?

☐ **(Check if Yes)**

(Please enclose a separate certificate to this effect)

17.Attached Documents:

Sl. No.	Document	Yes	No
1.	Covering letter		
2.	Approval letter from the head of the department/institution		
3.	Protocol of the proposed research		
4.	Ethical issue in the study and plans to address these issues		
5.	Investigator brochure		
6.	Informed consent form (English)		
7.	Informed consent form local/regional languages		
8.	Back translations of Informed consent forms		
9.	Translation and back translation certificates		
10.	Recruitment and retention material		
11.	Case report forms, subject diary, questionnaires, follow-up cards etc.		
12.	Where applicable translations of subject diary, questionnaires and follow-up cards		
13.	Where applicable back translations of translated subject diary, questionnaire and follow-up cards		

17.Attached Documents:

Sl. No.	Document	Yes	No
14.	Translation and back translation certificates of subject diaries, questionnaire and follow-up cards		
15.	Curriculum vitae of all the investigators with relevant publication in last five years		
16.	Medical registration certificate of all the investigators		
17.	GCP training certificates of all the investigators		
18.	Investigator undertaking		
19.	Form FDA 1572		
20.	Financial disclosure form from all the investigators		
21.	Regulatory clearance documents		
22.	Source of funding and financial requirement for the project		
23.	Other financial issues including those related to insurance		
24.	Any standard operating procedure to be followed, if applicable		
25.	Other site EC approvals, if applicable;		
26.	Statement of conflict of interest, if any		
27.	Any other information relevant to the study		
28.	CTRI number/document		
29	List of other documents submitted:		

17.Attached Documents:

Sl. No.	Document	Yes	No
	a:_____ b:_____ c:_____ d:_____ e:_____		

18. CTRI Registration Details

☐ **(Check if Done)**

Provide the details below:_____

Investigator Name		
Signature		**Date**

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Appendix-II
IEC APPOINTMENT LETTER

Date:

From

Director
Regional Institute of Ophthalmology
88, College Street, Kolkata-700073
West Bengal, India

To

_____
_____
_____

Subject: Constitution of Institute Ethics Committee

Dear Sir/Madam,

On behalf of Institutional Ethics Committee, Regional Institute of Ophthalmology, I request your concurrence for possible appointment as a member of Institutional Ethics Committee, Regional Institute of Ophthalmology.Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

Thanking you,

Signature & Date:
Name & Stamp:

Regional Institute of Ophthalmology

Medical College & Hospital
Kolkata-700 073

Appendix-III
IEC ACCEPTANCE LETTER

Date:
From

_____
_____
_____

To
Director
Regional Institute of Ophthalmology
88, College Street, Kolkata-700073
West Bengal, India

Subject: Consent to be a member of Institute Ethics Committee.

Ref.: Your Letter No.: _____ **Dated:**

Dear Sir,
In response to your letter stated above, I give my consent to become a member of Institutional Ethics Committee, Regional Institute of Ophthalmology.I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.
I shall be willing for my name, profession and affiliation to be published.
I shall not keep any literature or study related document with me after the discussion and final review.
I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.
I herewith enclose my CV.
Thanking you,
Yours sincerely,
Signature: _____
Name of the Member: _____ Date: _____
Address:
Telephone No: email:

Appendix-IV
IEC CONFIDENTIALITY AGREEMENT FORM

In recognition of the fact, that I_____
_____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC, and- have been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of Human subjects;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated

purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and the conditions set forth above. The original (signed and dated Agreement) will be kept on file in custody of the IEC. A copy will be given to you for your records. In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the information Act, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all confidential information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson Signature **Date**

I acknowledge that I have received a copy of this agreement signed by the EC Chairperson and me.

Signature **Date**

Appendix-V
IEC CONFLICT OF INTEREST FORM

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the Protection of human subjects.

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and should not participate in the IEC meeting or voting procedure.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.

- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I, _____ name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson Signature **Date**

I acknowledge that I have received a copy of this agreement signed by the IEC Chairperson and me.

_____ _____

Signature **Date**

Regional Institute of Ophthalmology

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Kolkata-700 073

Appendix-VII

ETHICS COMMITTEE APPROVAL LETTER TEMPLATE (TO BE PRINTED ON EC LETTER HEAD, IF EC LETTERHEAD NOT AVAILABLE, SEAL CONSISTING OF EC ADDRESS REQUIRED ON THE LAST PAGE)

Date: dd/mmm/yyyy

Reference no.:<Delete if NA>

To

<Name of the Principal Investigator>

<Name of the Institution>

<Address of the Institution>

Protocol Title:<Please mention the Protocol Title Here>

Protocol No.:<Please mention the Protocol Number/Version/Date Here>

Subject: Approval for the conduct of the above referenced study

Dear Dr.<Name of the PI>

With reference to your Submission letter dated <dd/mmm/yyyy>, Institutional Ethics Committee, Regional Institute of Ophthalmologyhas reviewed and discussed your application for conduct of clinical trial on <dd/mmm/yyyy>.

The following documents were reviewed and discussed:

Sr. No	Document	Document (Version/Date)
1.		
2.		
3.		
4.		

Regional Institute of Ophthalmology

Medical College & Hospital
Kolkata-700 073

The following members were present at the meeting held on <date, time & place>.

Sr. no.	Name of the Member	Designation and Qualification	Representation as per Schedule Y	Gender	Affiliation with the Institution
1.	<Name of the Member>	<Designation>& <Qualification>	< Basic Medical Scientist/ clinician/ Legal Expert/representative of non-governmental voluntary agency / philosopher / ethicist / theologian/ Lay Person>	<M/F>	<Y/N>

This is to confirm that only members who are independent of the Investigator and the Sponsor of the trial have voted/ provided opinion on the trial.
We approve the documents and the conduct of the trial in the presented form.

The Institutional Ethics Committee, Regional Institute of Ophthalmologymust be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and requests to be provided a copy of the final report.

The Institutional Ethics Committee, Regional Institute of Ophthalmologyfollows procedures that are in compliance with the requirements of ICH (international Conference on Harmonization) guidance related to GCP (Good Clinical Practice) and applicable Indian regulations.
Yours Sincerely,

_____

Member Secretary

Institutional Ethics Committee, Regional Institute of Ophthalmology
88, College Street
Kolkata 700073
West Bengal,India

(Seal of the Member Secretary)

Appendix – VIII

IEC Fee Details

IEC , Regional Institute of Ophthalmology will charge as per the below table:

Sr. no.	Initial EC fee (INR)	Amendment (INR)	Expedited review (INR)
1	35,000	10,000	40,000

The following categories of research projects may be exempt, at the discretion of the Committee, from submission of processing fees:

- Academic projects initiated by investigators without formal funding i.e. funding beyond their personal and departmental resources.
- Projects initiated by postgraduate or postdoctoral medical trainees, as part of their doctoral dissertation / thesis, using their own protocol.
- Projects initiated by other categories of students and research scholars, in fulfillment of their curricular requirements, using their own protocol.

The committee may also levy a service fee for issue of duplicate approval letters and for providing duplicates of documents submitted to the committee, when such documents are required by the PI for some reason.

The quantum of such fee at present at Rs. 500/-(Indian Rupees five hundred) only plus any photocopying costs, if applicable, at actuals.

All payments to the Committee are to be made by Account payee cheque or Bank draft, drawn in favors of **RIO, Research Committee** and payable at Kolkata.

Chairman and Member Secretary, IEC, RIO, Will jointly operate the dedicate account of the Committee in a nearby bank. When persons in these posts change, they will intimate the bank along with the name of the incumbent who is to become the new signatory. This is to be done without delay so that the bank can update its records and the activities of the IEC do not suffer.

The Member-Secretary will maintain the books of accounts of the Committee which will be open to inspection by the members of the Committee.

REFERENCES

a. ICMR guidelines 2017. Available at: https://icmr.nic.in/

b. Declaration of Helsinki 2013. Available at: https://www.wma.net/

c. NABH Accreditation Standards for Ethics Committees 2016.Available at: https://www.nabh.co/CT_Standard.aspx.

d. ICH-GCP (E6) R2 2016. Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf.

e. New Drug CT rules,2019 available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf