

# Narayana Nethralaya Ethics Committee Standard Operating Procedures (SOP)



## 1. Objective:

The objective of the 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 (Indian Council of Medical Research).

## 2. Role of 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 goals of research, however important, should not be permitted to override the health and well-being of the research subjects.

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 benefits and provisions for appropriate compensation wherever required. It will review the proposals before the start of the study as well as monitor the research throughout the study through appropriate and well-documented procedures. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the IEC will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.

## 3. Composition of IEC

The number of members in the IEC at Narayana Nethralaya will be thirteen. A minimum of five members will be required to compose a quorum.

The IEC shall be constituted in the following pattern-

- i) A chairperson
- ii) A Member-secretary
- iii) Other members from different disciplines.

The chairperson of the IEC shall be from outside Narayana Nethralaya to maintain the independence of the Committee. The member-secretary shall belong to Narayana Nethralaya and conduct the business of the Committee.

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Version No. 002;  
Dated: 01/11/2009

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There shall be adequate representation of age, gender, community etc in the IEC to safeguard the interests and welfare of all sections of the society. Members shall be aware of the local, social and cultural norms.

If required, subject experts will be invited to present their views; or depending on the research subject, specific patient groups (eg: HIV positive) will be represented in the committee.

#### 4. Authority under which IEC is constituted:

The Institutional Head Constitutes the IEC.

#### 5. Membership Requirements:

- The duration for appointment is initially for a period of 2 years.
- At the end of 2 years, the committee shall be re-constituted and 50% of the members shall be replaced.
- A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines.
- A member can tender resignation from the committee with proper reasons to do so.
- All members should maintain absolute confidentiality of all discussions during the meeting.
- Conflict of interest should be declared by members of the IEC.

#### 6. Quorum requirements:

The minimum of 5 members is required to compose a quorum, of whom at least one should be from outside the institute. All decisions should be taken in a meeting and not by circulation of project proposals.

#### 7. Offices:

The Chairperson will conduct all meetings of the IEC. If for 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. 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 the Chairperson before communicating to the researchers with the approval of the appropriate authority.

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### **8. Independent Consultants:**

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, 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. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

### **9. Application procedures:**

- a. All proposals should be submitted in the prescribed application form, the details of which are given under documentation.
- b. All relevant documents should be enclosed with application form.
- c. Required number of copies of the proposal (14 copies) along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators should be forwarded directly to the IEC.
- d. The date of the meeting will be intimated to the researcher, to be present, to offer clarification.
- e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

### **10. Documentation:**

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

1. Name of applicant with designation.
2. Name of the institution where the research will be conducted.
3. Approval of the Head of the Institution
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address those issues.
6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow-up cards etc.
7. Informed consent process, including patient information sheet and informed consent form in local language and English.
8. For any drug/device trial, all relevant pre-clinical animal data and clinical data from other centers within the country/ other countries, if available.
9. Curriculum vitae of all the investigators.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.

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12. Other financial issues including those related to insurance.
13. An agreement to report Serious Adverse Events (SAE) to the IEC.
14. Statement of conflict of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.
16. A statement describing any compensation for study participants (including expenses and access to medical care to be given to the research participants; a description of the arrangement for indemnity, if applicable (in study-related injuries); 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 a 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 reason for negative decisions should be provided.
17. Plans for publication of results- positive or negative- while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study.

### 11. Review procedures:

- a. The meeting of the IEC shall be held every month, and additional meeting may be held as and when proposals are received for review.
- b. The proposals shall be sent to the members at least 2 weeks in advance.
- c. Decision will be taken by consensus after discussion, and whenever needed voting will be done.
- d. Researchers will be invited to offer clarification if need be.
- e. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed. The decision to invite an independent expert may be taken by the Chairperson and one member.
- f. The decisions will be minuted and the chairperson's approval taken.

### 12. Elements of Review

- a. Scientific design and conduct of the study.
- b. Approval of appropriate scientific review committee.
- c. Examination of predictable risks/harms.
- d. Examination of potential benefits.
- e. Procedure for selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues.
- f. Management of research related injuries.
- g. Compensation provisions.
- h. Justification for placebo in control arm, if any.
- i. Availability of products after the study, if applicable.
- j. Patient information sheet and informed consents in local language.

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- k. Protection of privacy and confidentiality.
- l. Involvement of community wherever necessary,
- m. Plans for data analysis and reporting.
- n. Adherence to all regulatory requirements and applicable guidelines.
- o. Competence of investigators, research and supporting staff.
- p. Facilities and infrastructure of study sites.
- q. Criteria for withdrawal of patients, suspending or terminating the study.

### 13. Expedited review:

All revised proposals, will be examined by the entire committee. The time of review is to be stated by the committee giving due consideration to the aim of expediting the process.

### 14. Decision making:

- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member shall 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.
- c. Decision will be made only in meetings where the quorum is complete.
- d. Only members can make the decision. The expert consultants will only offer their opinion.
- e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed shall be specified.
- g. Modified proposals will be reviewed by an expedited review through full committee.
- h. Procedures for appeal by researchers shall be defined.

### 15. Communicating the decision:

- a. Decision will be communicated by Member-secretary in writing.
- b. Suggestions for modifications, if any, shall be sent by IEC.
- c. Reasons for rejection shall be informed to the researchers.
- d. The schedule/ plan of ongoing review by the IEC shall be communicated to the PI.

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### 16. Follow-up procedures

- a. Reports should be submitted at each meeting by the principal investigator for review.
- b. Final report should be submitted at the end of the study.
- c. All SAEs and the interventions undertaken shall be intimated immediately.
- d. Protocol deviation, if any, shall be informed immediately with adequate justification.
- e. Any amendments to the protocol shall be re-submitted for renewed approval.
- f. Any new information related to the study should be communicated.
- g. Premature termination of study should be notified with reasons along with the summary of the data obtained so far.
- h. Change of investigators/sites should be informed immediately.

### 17. Record keeping and archiving:

- a. Curriculum vitae of all members of IEC.
- b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
- c. Minutes of all meetings duly signed by the chairperson/Member-Secretary.
- d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- e. Copy of correspondence with members, researchers and other regulatory bodies.
- f. Final report of the approved project.

**Note:** Institutional Ethics Committee also operates as per ICH-GCP Guidelines and the Schedule Y.

Dr. SriBhargava Natesh,  
Member-Secretary  
Narayana Nethralaya Ethics Committee  
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