INSTITUTIONAL ETHICS COMMITTEE

Govt: College of Nursing
Kottayam
PIN : 686008

STANDARD OPERATING PROCEDURES

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IEC SOP
Version:
Date:

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Formats

1. Introduction

Objective:

The objective of this SOP is to contribute to the effective functioning of the IEC at 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

2. Authority and Administrative office of IEC

- The Principal or equivalent person from the Institution has the authority for constitution of Ethics Committee.
- Chairman is the Head of IEC and he/she will be appointed by the Head of the Institution.
- All other EC members are appointed by the Head of the Institution in consultation with chairperson / Member Secretary.
- The office of Member secretary will act as the administrative office of IEC.
- 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 circulated to all the members. The final minutes of the meeting will be kept in the minutes of the meetings file signed by the Chairman/ Member Secretary.

Name of Head of the Institution:	Dr. Usha V.K
Mailing address:	Govt. College of Nursing Gandhinagar P.O Kottayam Pin: 686008
Contact No:	04812598871
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Name of the Chairman of EC:	Dr. P.Sukumaran
Mailing address:	Govt. College of Nursing Gandhinagar P.O Kottayam Pin: 686008
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Fax:	
Email:	sukuparakal@gmail.com
Name of the Member Secretary:	Dr.Liny Joseph
Mailing address:	Govt: College of Nursing ,Gandhinagar P.O Kottayam Pin code :686008
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Email:	linyjsunny@gmail.com

3. Terms of reference of the committee

- To improve the standards of the ethics practiced in the hospital.
- To ensure that all proposed research projects conform to regulatory requirements.
- To function as a forum to resolve the complaints on ethical issues from patients and their families.

4. Responsibilities of IEC

- To protect and safeguard the dignity, rights, safety and well being of all actual or potential research participants.
- To ensure that the research projects that are carried out are sound in design, have statistical validity and are conducted according to the ICMR, Schedule Y and ICH/GCP guidelines
- To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethic consideration.
- To provide advice to the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research.
- Are conducted under the supervision of trained medical / bio medical persons with the required expertise
- Include, solely, patients or participant who have given voluntary and informed consent
- It may be ensured that no research project shall be / can be started unless Ethics Clearance / Approval is obtained and that no retrospective / post facto Ethics Clearance
- It will review the proposals before start of the studies as well as monitor the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

5. Composition and Membership requirements of Ethics Committee

Composition of IEC:

- IEC will have a chairman from outside the organization
- The chairman, the member secretary and other members are nominated by the Director.
- IEC will have minimum of Seven (7) members.
- It is mandatory to have the following category of members to represent multidimensional structure.

a) Legal expert
b) Basic Medical scientist
c) Clinician
d) Social Scientist or Non Governmental Voluntary Agency representative or Philosopher or

Ethicist or Theologian or a similar person

e) Lay person from community

Membership requirements:

- The members are drawn from different specialties to give a multi-sectorial, multidimensional structure. A one page Curriculum Vitae (CV) will be collected from each member and filed in the administrative file.
- The duration of appointment is initially for a period of 3 years
- At the end of 3 years, the committee is reconstituted, by the discretion of the management.
- A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so, which should be acceptable to the DCGI, ICMR.
- All members should maintain absolute confidentiality of all discussions during the meeting. A confidentiality agreement will be signed from each member and filed in the administrative file.

6. 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, 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 the members of the IEC.

7. Quorum requirements

At least one person from all the above 5 representation are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. The attendance register / log will be filled to document the quorum of the meetings

8. Procedure for resignation, removal and replacement of members

- A member can submit resignation to chairman of the EC with a minimum notice period of one month, mentioning the valid reason for the resignation. It can be approved by the head of the Institution in consultation with chairperson / Member Secretary.
- A member may be relieved or terminated of his/her membership in case of: (a) conduct unbecoming for a member of the Ethics Committee (b) Inability Relocate to another city or any such matter.

- In case of resignation of a member, Head of institution will appoint a new member falling in the same category of membership. Appointment may be made in consultation with the chairperson / Member Secretary.
- A member may be removed/ terminated of his/ her membership in case of failure of attending the last 3 consecutive ethics committee meetings.
- The respective communication shall be maintained at the Ethics committee records.

9. Meeting Procedures

- The IEC meetings are held annually. Additional meetings may be held as and when considered necessary.
- The Investigator's team should submit the documents 3 weeks prior to the scheduled meeting to IEC. The applicant of a proposal is required to submit 07 copies of his / her application letter and copies of the documents.
- The notice of each meeting with the agenda is sent out to the members at least one week before the meeting.
- A quorum is required for all meetings. The project can be approved unanimously or by non-unanimously. When it is approved unanimously, an approval letter will be prepared and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- Member secretary will prepare the minutes of the meetings and circulated to all the members. The final minutes of the meeting will be kept in the minutes of the meetings file signed by the Chairman.

10. Minimum required documents for submission of research project for approval.

- Trial Protocol: Submit the latest protocol along with all the amendments mentioning the version no. (s) and date(s).
- Patient Information Sheet and Informed Consent Form: Submit the latest Patient Information Sheet(s) and Informed Consent Form (s) in English and all t he vernacular languages mentioning the version no . (s) and date(s).
- Investigator's Brochure: Submit the latest Investigator' brochure mentioning the version no. (s) and date(s).
- Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
- Principal Investigator's signed and dated current CV along with medical registration certificate.
- Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
- Investigator's Agreement with the Sponsor.
- Investigator's undertaking, as per Schedule Y – Appendix VII format.
- The Regulatory approval / status report from sponsor for the conduct of study.

- A description of the process to be used to obtain the informed consent.

11. Element of review

- Scientific design and conduct of the study.
- Approval of appropriate scientific review committees.
- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects: Exclusion/ Inclusion criteria
- Management of research related injuries, side effects, ADRs.
- Compensation provisions.
- Justification for placebo in control arm, if any.
- Availability of products after the study, if applicable.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary.
- Plans for data analysis and reporting
- Adherence to all regulatory requirements.

12. Decision-making

The committee will give its opinion on the project in writing in one of the following ways:

- Members will discuss the various issues before arriving at a consensus decision.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or modify the proposals. Specific suggestions should be given for modifications.
- Modified proposals may be reviewed by an interim review through identified members.
- Negative decisions should always be substantiated by appropriate reasons.
- The project can be approved unanimously or by non-unanimously. When it is approved unanimously, an approval letter will be issued and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- The chairman / member secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made.
- This decision will be ratified at the next full committee meeting and minted.

- All documents pertaining to the Institutional Ethics Committee will be held in the office of the Member Secretary of Institution Ethics Committee

13. Communicating the decision

- Decision will be communicated by the Member Secretary in writing.
- Any suggestions to IEC, if any, should be sent for modifications.
- Reasons for rejection should be informed to the researchers. There is no need to communicate the name of the specific expert or member who made the review.

14. Follow up review procedures

- Regular reports should be submitted for regular review.
- Final report to be submitted at the end of study.
- Any serious side effects, adverse drug reactions and the interventions undertaken to be intimated.
- Protocol deviation, if any, to be informed with adequate justifications.
- Any new information related to the study should be communicated.
- Premature termination of study should be notified with reasons and summary of the studies done so far.
- A study status report should be submitted to EC every 6 months.

15. Expedited / Interim review

- All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members decided by the Chairman to expedite decision making.
- Such expedited review may also be taken up in cases of relevant proposals requiring urgent review.
- The decision of discussing a project in the expedited manner is given by the chairman.

16. Self-assessment

IEC should have a self-assessment system to ensure the effective functioning of IEC. Self-assessment will be performed for each member. The self-evaluation will be done annually. Ethics committee will form a committee within the members to assess the functioning of IEC annually to ensure the following.

- Functioning of IEC
- Attendance and Participation of Members

- Training and Certifications of Members
- Record Keeping and Archival
- Income and Expenditure of IEC
- Periodic Monitoring and Review
- SAE Management process
- Documentation Management
- Administrative Support
- Performance of Members

The member secretary and Chairperson will do the self-assessment. Member Secretary will perform assessment of the members and report to the Chairperson.

17. Review of Serious Adverse Event (SAE) Reports and Recommend Compensation

- Investigators who are participating in the clinical trial from the Institution are requested to strictly follow the reporting and review guidelines of the SAE as per the local regulations of the country.
- As per the regulation Investigator has to submit the initial report of SAE to EC within 24 hours of SAE occurrence. Investigator can submit the SAE report to EC via an email / Fax / by-hand.

Ethics committee E-mail ID and Fax No. for 24-hr SAE submission	
Ethics committee Email:	
Ethics committee Fax No:	

- The investigator has to submit the initial report of SAE to respective sponsor within 24 hours of SAE occurrence.
- The investigator has to submit the initial report of SAE to the Higher Authority within 24 hours of SAE occurrence at the below mentioned Email ID/Fax No.

Higher Authority E-mail ID and Fax No. for 24-hr SAE submission	
Higher Authority Email:	**dci@nb.nic.in**
Higher Authority Fax No:	**01123236973**

- The investigator and Sponsor have to submit the analyzed report of SAE to the EC Chairman, Head of the Institution and HA within 14 calendar days of SAE occurrence.
- On receipt of the analyzed report of SAE from the Investigator, the EC will evaluate and give opinion on financial compensation to be paid by the Sponsor/ his representative.

- A detailed report of recommendation of compensation will be submitted to the HA by EC within 30 calendar days of SAE occurrence.

- The review of reports could be done through a meeting, teleconference, email or telephonic conversation.

18. Types of Clinical research reviewing by the Ethics Committee

- The Ethics Committee will review Pharmaceutical studies, epidemiological studies, retrospective studies, herbal studies and studies for devices.

19. SOP for Vulnerable Population

- A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
- Prime attention and care would be taken to evaluate the safety and well being when the vulnerable category of subjects participating in a clinical trial. The local regulation in the country would be taken as the standard of evaluation.

20. Policy regarding Training and Updating IEC members

- All relevant new guidelines to be brought to the attention of the members.
- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.
- All EC members must be conversant with ICMR Guidelines for Research involving Human Subjects, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
- All the members will be given training on the above-mentioned guidelines and rules yearly basis. A training record would be maintained for the same.
- Every new member will get trained on all of the above-mentioned guidelines and rules at the time of appointment.
- When a new rule/ guideline / sop revision has happened, all the members would be trained and training record would be maintained for the same.

21. Policy to prevent conflict of interest

- The ultimate interest of Ethics committee is to prevent conflict of interest.
- It has been recognized that the potential for conflict of interest will always exist, but Chairperson is capable to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

- There should be no conflict of interest.
- The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes.
- All members shall sign a declaration on conflict of interest.

22. The committee expects from the investigators

- A progress report on six monthly bases or more frequently as the committee feels it.
- A report of each serious event when observed during the conduct of the study
- To keep informed of amendments to any study related documents
- To keep informed of study discontinuation with reasons.

23. Archiving/Record keeping

All the following documents will be archived for 5 years from the date of the Study close out. Some documents which are archived, but not limited to the following.

- Curriculum Vitae (CV) of all members of IEC.
- Copy of all study protocols with enclosed documents, annual reports, side-effects/ADRS etc.
- Minutes of all meetings with due signature of Chairperson.
- Copy of all existing national and international guidelines on research ethics.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Final report of the approved projects.

Format 1: Consent to be a member of IEC

Date:

To

The Chairman
<<enter hospital name and address>>

Sub: Consent to be a member of IEC

Sir,

I accept the invitation to become a member of IEC of <<enter hospital name>>

I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing to publicize my full name, profession and affiliation.

I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC.

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 any one other than project related personnel.

I herewith enclose my CV

Thanking You,

Yours sincerely,

Signature ----------

Name of Member---------- Date

Address and Telephone No:

Format 2: One page Curriculum vitae
Institutional Ethics Committee
<<enter hospital name and address>>

Curriculum Vitae

NAME	:	
QUALIFICATIONS	:	
MEDICAL REG. NO. (if applicable)	:	
PRESENT ADDRESS	:	
TELEPHONE No.	:	
EMAIL ID	:	
PROFESSION	:	
AFFILIATION (S)	:	

Sign: _____

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Date: _____

Format 3: Confidentiality agreement for members

Institutional Ethics Committee
<<enter hospital name and address>>

Confidentiality Agreement

1. I understand that I being a member of Institutional Ethics Committee, <<enter hospital name>>, I may acquire or may have already acquired knowledge of or access to, information concerning with the various research studies from companies.
2. I understand that this confidential information is the exclusive property of the study sponsor / <<enter hospital name>>. I understand to keep this information strictly confidential. I will not disclose to any third party the information and contents of the confidential documents without prior written consent from Institutional Ethics Committee. I understand that this applies for a period of 2 years from the date of my induction into Institutional Ethics Committee.

Signature : _____

Name : _____

Date : _____

Format 4: CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

<<Please mention the date of this committee formation and tenure period>>

S. No	Name of the Member, Gender and Qualification	Role at IEC	Affiliation
1			
2			
3			
4			
5			
6			
7			
8			

Signed and dated by Chairman & with EC seal.

Format 5: Template for submission of Research Proposal

<< On Institution Letter Head>>>
<< EC Tracking No. >>
Date:

To
The Member Secretary
Institutional Ethics Committee
<<Enter Address>>
.

Ref: <<<….. Protocol Name and Number……>>>

Sub: <<…..Submission of Study Documents to EC for review and Approval ……>>

Dear Sir/Madam,

Please find enclosed 10 copies of following documents of the above mentioned project for forthcoming Institutional Ethics Committee (IEC).

<<<<……. List of Documents with version no. and date…….>>>>

I wish to assure you that the study would be initiated at the site only after approval of the Ethic Committee.

Please revert for additional information and clarifications.

Thanking you,

Yours Sincerely,

<<<…. Principal Investigator's Name, Designation …..>>>
Principal Investigator (Protocol Number)

TO WHOM IT MAY CONCERN
We here by confirm the receipt of the above referenced documents submitted to us.

Signature , Date and Ethics Committee Seal

Format 6: Template for IEC approval letter

INSTITUTIONAL ETHICS COMMITTEE

Date

To,
<<PI Name and project code>>.

Ref: Study Protocol- <<protocol ID and Title>>

Sub: Ethics Committee approval

Dear <<PI Name>>,
The Institutional Ethics Committee, <<enter site name>>, reviewed and discussed your application dated <<Date of Submission>> to conduct the clinical trial entitled <<Title of the study>> on <<Date of EC meeting held>>.

The following documents were reviewed and approved:

<<List the documents which are reviewed and approved and reviewed only – separately>>
The following members of the Institutional Ethics Committee were present at the meeting held on <<date of EC meeting held>>.

<<List the members name and their role in the IEC in the box below>>

S#	Name	Role in the Ethics Committee
1		
2		
3		
4		
5		
6		
7		
8		
9		

Case 1. <<In case study was unanimously approved follow the below pattern>>
The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study. One member was abstained from voting (<<write the name of the members who abstained from voting)

IEC SOP
Version:
Date:

Case 2. <<In case study was non-unanimously approved - follow the below pattern>>
The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study as against <<Votes against - write here>> votes against the study. One member abstained from voting (<<write the name of the members who abstained from voting).

We confirm that principal investigator did not participate in the deliberations of the ethics committee for this study and did not vote on the proposal for this study.

Please submit the following documents before recruiting the patients in to the study.

<<List the documents which has to be submitted to the IEC before the study to be initiated at our center>>

Please note that you should follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by the IEC without the prior written approval of this ethics committee. Deviations/ changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to the IEC:

- Any changes to or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial subjects.
- All serious adverse events.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit to the IEC, the status report of the study at every 6 months interval.
Please provide a close out report to the Ethics Committee on the completion of the study.

The IEC is organized and operates according to the requirements of ICH - GCP and requirements of the Indian Council of Medical Research (ICMR) and Schedule Y.

Thank you for your time and efforts.

Cordially,

<<Name of Chairman>>
Chairman
Institutional Ethics Committee
<<Enter Address>>.

<<Name of Member secretary>>
Member Secretary
Institutional Ethics Committee

<<Enter Address>>.

IEC SOP
Version:
Date:

APPROVAL

This document has been approved by:

Function	Name	Signature	Date (DD-MM-YYYY)
IEC Chairman			
IEC Member Secretary			