ISTITUTIONAL RESEARCH COMMITTEE

The Institutional Research Committee is responsible for ensuring an appropriate and sustainable system for quality ethical review and monitoring. The IRC is responsible for scientific and ethical review of research proposals. IRCs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research. The IRC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs. The IRC should be competent and independent in its functioning

VISION

- To promote the nursing students to safeguard the dignity, rights and well being of the participants by providing ethical guidelines, education in ethical principles, and the necessary resources to monitor and implement ethical decisions.

MISSION

- The resolution of ethical problems requires an Institutional Research Committee which is multidisciplinary and multispectral in composition, includes relevant scientific and legal expertise, with balanced age, gender and ethnic distribution, as well as lay persons representing the concerns of the wider community.
- This committee will lay down appropriate guidelines based on established ethical principles, and in accordance with the values of the community.

OBJECTIVES

- Formulate and publish Ethical Guidelines for Indirani College of Nursing.
- Ensure these guidelines are understood and accepted by the wider participants.
- Provide a mechanism for arranging consultation on urgent ethical problems.
- Periodic review of ethical decisions taken to ensure they fall within the guidelines provided.
- Ethical review of research protocols and the conduct of research at Indirani College of Nursing

1. **Functions**

- IRC has to ensure protection of the dignity, rights, safety and well-being of the research participants
- IRC is responsible for declaration of conflicts of interest to the Chairperson
- IRC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner
- IRC must ensure ethical conduct of research by the investigator team
- IRC should assist in the development and education of the research community in the given institute
- IRC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected
- IRC reviews progress reports, final reports and gives needful suggestions
- Regarding care of the participants and risk minimization procedures, if applicable
- IRC should recommend appropriate compensation for research related injury, wherever required
- IRC should carry out monitoring visits at study sites as and when needed

STANDARD OPERATING PROCEDURE (SOP) FOR INSTITUTIONAL RESEARCH COMMITTEE

1. Objective

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

2. Constitution of IRC

In consultation with the Academic Board the institution shall constitute the institutional research committee in the following pattern:

1. Chairperson
2. Member Secretary from Institute

3. 5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.
4. The committee will be normally reconstituted every 3 years

3. **Composition**:

- IRC should be multi-disciplinary and multi-sectoral.
- There should be adequate representation of age and gender.
- Preferably 50% of the members should be non-affiliated or from outside the institution
- The number of members in an IRC should preferably be between 7to15 and a minimum of five members should be present to meet the quorum requirements.

The composition may be as follows:-

1. Chairperson
2. Basic medical scientists
3. Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Educated person from the community
7. Member-Secretary

4. Institutional Research Committee Members:

S.NO	NAME OF THE MEMBER	DESIGNATION	PHONE NO	MAIL ID
1.	Dr.Renuga.K Principal - KGNC	Chairperson	9486537848	principal@kgnc.ac.in
2	Dr.Rathidevi.S HOD-Community Health Nursing	Member Secretary	960063477	rathidevi@icon.ac.in
3.	Dr.Malliga Kannan Principal,ICON	Basic Medical Scientist	9444884034	principal@icon.ac.in
4.	Dr.Pahinian.A Principal - SVCPMS	Basic Medical Scientist	9842698683	principalsvcopt@gmail.com
5.	Dr.Rajeswari.R Vice Principal	Basic Medical Scientist	9344318568	viceprincipal@icon.ac.in
6.	Prof. Sunitha Therese HOD-Medical Surgical Nursing	Basic Medical Scientist	8220429483	sunithatherese@icon.ac.in
7.	Prof.Ganesan.E HOD-Mental Health Nursing	Basic Medical Scientist	9047015208	ganesan@icon.ac.in
8.	Prof.Jamunarani.G HOD-Obstetrics and Gynecological Nursing	Basic Medical Scientist	8248989482	jamunarani@icon.ac.in
9.	Mrs.Chandraleka.E HOD - Chid Health Nursing	Basic Medical Scientist	9751111024	echandraleka@icon.ac.in

10.	Dr.Prabhu , Professor Department of Medicine SVMCH&RC	Clinician	9994469930	kggprabhu@gmail.com
11.	Mr.Sai Radjachandran	Legal Experts	9443086411	-
12.	Mr.Muthuvenkadasubramanium - Sociologist	Social Scientist	8056694545	muthusiksha@gmail.com
13.	Dr.Senthil - Psychologist	Social Scientist	99442-80600	psysendhil@gmail.com
14.	Dr.Visalakshi	Social Scientist	9894581310	-
15.	Rev. Sr. Samuela Adaikalam,	Lay Person	9486267998	mailto:Samuelafihm@gmail.com

5. Membership Duration and Responsibilities

- The duration of the membership will be 3 years
- There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
- A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Director.
- Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- Conflict of interest if any shall be declared by members of the IRC at the beginning of every meeting.

6. Quorum Requirements

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and **not by circulation of project proposals.**

7. Conduct of the Meeting

The Chairperson will conduct all meetings of the IRC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the principal investigator.

8. Independent Consultants

IRC may call upon subject experts as consultants for review of selected research protocols. 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 will not take part in the decision making process.

9. Application Procedure

- All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
- All relevant documents should be enclosed with application.
- The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the principal investigator and Co-investigators / Collaborators should be forwarded by the Head of the Department.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
- The date of meeting will be intimated to the principal investigator who should be available to offer clarifications if necessary.
- The decision of IRC will be communicated in writing. If revision is to be made, the revised document in the required number of copies should be submitted within a stipulated period of time as specified in the communication.

10. Documentation

All research proposals should be submitted with the following documents:

1. Title of the project
2. Name of any other Institute/Hospital/Field area where research will be conducted.
3. Approval of the Head of the Department.
4. Ethical issues in the study and plans to address these issues.
5. Proposals should be submitted with all relevant annexure like proforma, questionnaires, interventions, modules, follow–up cards, etc. to be used in the study.
6. Patient information sheet and informed consent form in English and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them.
7. Source of funding and Budget along with the supporting documents.
8. An undertaking to immediately report Serious Adverse Events (SAE) to IRC.
9. Statement of conflicts of interest, if any.
10. Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
11. Agreement to submit final report at the end of study.

11. Review Procedure

1. Meetings of IRC shall be held on scheduled intervals as prescribed **(once in 3 months**, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. Principal investigator should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants / Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with signature of Chairperson at each page.

12. Element of Review

1. Scientific design and conduct of the study.
2. Assessment of predictable risks / harms and potential benefits.
3. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
4. Management of research related injuries, adverse events and compensation provisions.
5. Patient information sheet and informed consent form in English and local language.
6. Protection of privacy and confidentiality of subjects.
7. Involvement of the community, wherever necessary.
8. Protocol and proforma of the study including the consent form.
9. Plans for data analysis and reporting.
10. Competence of investigators, research and supporting staff.
11. Facilities and infrastructure.

13. Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IRC for clearance and approved by the Chairperson. The approvals will be reported in the next IRC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

14. Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IRC.

i) Principal investigator (PI) should submit the ongoing project on format prescribed by the Institute, to the IRC.

ii) The final report of the completed study should be submitted by PI.

iii) The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IRC.

15. Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

16. Follow up Procedures

1. Final report should be submitted at the end of study in prescribed format including a copy of the report which has been sent to the sponsoring agency.
2. Protocol deviation, if any, should be informed with adequate justifications.
3. Any new information related to the study should be communicated to IRC.
4. Premature termination of study should be notified with reasons along with a summary of the data obtained so far.
5. Change of investigators should be done with the approval of IRC.

17. Record Keeping and Archiving

1. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
2. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
3. All study related documents should be archived for minimum of ten years after the completion of study.
4. Final report of the approved projects.