CHOITHRAM COLLEGE OF NURSING

INSTITUTIONAL ETHICAL COMMITTEE

CODE OF ETHICS

RESEARCH ETHICS COMMITTEE

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INTRODUCTION

The aim of this code of ethics is to offer a constructive and attainable list of recommendations for upholding honesty in nursing research. To protect the rights and wellbeing of the people, groups, or community being studied, the nurse researcher must adhere to these moral standards when performing nursing research. Research ethics are essential to evidence generation, nursing education, and research practice. In addition, planning how to handle the problems in research, nurse researchers should have an awareness of and expertise in research ethics. Respecting these guidelines will guarantee research participants the utmost in terms of privacy, confidentiality, disclosure of information, and fair treatment.

Primary goal of institutional ethics committee,

The main objective of the Institutional Ethics Committee is to guarantee that the welfare and rights of human subjects are sufficiently safeguarded in any research. The Institutional Ethics Committee, will help the investigators accomplish this goal by helping them design their research projects to minimize potential

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harm to human subjects, reviewing all planned research involving human subjects before the research begins, approving research that satisfies established standards for the protection of human subjects, and monitoring approved research to ensure that human subjects are protected.

Protocol for ethical clearance for researches of Choithram College of Nursing

- Choithram Hospital **& Research Centre** has an Institutional Ethical Committee. This committee is responsible for the implementation of the ethical principles of various research conducting in the institution. The IEC shall observe the National Ethical guidelines for Biomedical and Health Research involving human participants, specified by the Indian Council of Medical Research (ICMR).
- As Choithram College of Nursing has to undertake the projects of post graduate and undergraduate students, it has a separate ethical committee, consisting of 7 members from the College of Nursing in order to ensure its ethical aspects.
- The projects which include clinical trials or interventional studies shall be submitted to the Institutional Ethical committee of Choithram Hospital **& Research Centre** for further ethical clearance.

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Guiding principles of IEC

- If the serious events are a result of breach of protocol (intervention), the committee may recommend disciplinary action against those who are responsible while allowing the continuation of the study without changes in the protocol.
- If the research intervention a reasonable possibility of being cause of the serious events in question, the study must be put on hold with a systematic reversal, safe guarding the health and wellbeing of the subject while the cause is being determined. After the cause is identified the study may continue with appropriate changes in the study protocol or the committee may recommend termination as appropriate.
- If the cause of events cannot be ascertained and the seriousness of adverse event is such that continuation of the study may cause a significant threat to life of may cause permanent disability, the committee is obliged to recommend termination.
- If the sponsor and the investigators desire termination, the same may be recommended noting the specific reason for termination as provided by them.

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Authority and Administrative office of IEC

- The lECs should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC.
- The Principal or equivalent person from the Institution has the authority for the 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 number of people in an ethics committee should be kept fairly small (8- 12 members).
- The members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the differed points of view.
- 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.

The composition may be as follows: -

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1. Chairperson (who is from outside the institution)
2. One-two persons from basic medical science area
3. One-two clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist/representative of non-governmental voluntary agency
6. One philosopher/ethicist/theologian
7. One lay person from the community
8. Member Secretary
9. One Female member (Gender Representation)

Rules and responsibilities of the IEC and its members

The Committee shall:

- Conduct independent and competent ethical reviews of research proposals.
- Review proposals within a fair time frame and provide written feedback to applicants.
- Fostering a research community that addresses local healthcare needs.

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- Protect the rights, dignity, safety, and wellbeing of fall study participants as well as communities.
- Giving particular attention to studies that could involve people who are at risk.
- Ask the researcher(s) to address any study component that would necessitate a face-to-face appearance at the committee meeting.
- Provide guidance to the investigator on all aspects of the welfare and safety of research participants.
- Ensure scientific soundness of the proposed research.

Role of Chairman

- Chair the meetings
- Facilitate and participate in IEC educational activities
- Keep abreast of regulations and policies governing IEC review of research and the conduct of human subject's research
- Appoint IEC members

Role of the Secretary

- Organization of an effective and efficient tracking procedure for each proposal received Preparation, maintenance and distribution of study files
- Organization of regular IEC meetings
- Preparation of the agenda and the minutes of the meetings
- Maintenance of the IEC records
- Communication with IEC members and investigators

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- Providing the necessary administrative support for IEC related activities to the chairman of the committee.
- Correspondence with the chairman and IEC members, with investigator and with regulatory authority

General role of all members

- The members' (including chairman and secretary) primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research subjects.
    - Participate in the IEC meeting
    - Review and discuss research proposals assigned for evaluation.
    - Monitor site for adverse events and recommend appropriate action(s)
    - Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest if any–such discloser shall be sufficiently detailed and timely to allow the IEC administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet quorum.
- The IEC member/ consultant shall evaluate whether a conflict of interest exists, and he / she shall disclose any identified

conflict to the IEC at the next IEC meeting. If an IEC member discovers that he / she has a conflict of interest during the conduct of a study over which the IEC provide oversight, the IEC member - consultant shall report the conflict to the IEC. Other IEC members shall cooperate with the IEC and other officials in their review of conflicts of interest issues and shall comply with all requirements of the IEC.

- Carry out work delegated by the chairperson, co-chairperson and/or member secretary.
- Participating in continuing educational activities on ethics and research.

Operational mechanism procedure for meeting

- Meetings shall be scheduled approximately twice a year based on the load of the proposals.
- Exact meeting dates shall be notified at least three weeks in advance so that all members can make themselves available for the purpose.
- The Secretary shall be the convener with responsibility for organizing the meetings, maintaining the records, laying out the agenda and communicating with the all concerned about the meeting.
- He/she shall prepare the members and get it approved by the

chairperson before communicating decision of the IEC to the investigators.

The meeting must demonstrate and document the following deliberations:

- The presence of full quorum
- Declaration of conflict of interest
- Confirmation of last meetings minutes
- Details of risk- benefit assessment decision of review (initial, continue review) of study
- Any changes requested

- The IEC secretary prepares the agenda a week prior to the IEC meeting and circulates the agenda via e- mail.
- Schedule studies on the agenda. The number of items is based on available expertise (members and consultants) urgency, order of submission to the IEC and IEC workload.
- An IEC member who has a conflict of interest with regard to a research project that will be reviewed at a convened IEC meeting must be notified the IEC office of the conflict prior to the meeting.
- Once the IEC office receives notice of refuse, the IEC secretary will seek an alternate IEC member to join the meeting for the review of that project if necessary to meet quorum.

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- The copies of the protocol / documents shall be sent to the IEC members while either electronic mail (in case of electronic submission of protocols) or by courier of hardcopies and CD preferably 10 days in advance of the scheduled meetings

- **Quorum requirements:**

- All research projects for approval by the full board of the IEC shall be reviewed convened meetings at which the majority of the members of the IEC are present
- The presence of the following 5 members is required to form part of the quorum without which a meeting cannot be convened and a decision regarding the project cannot be taken. (Scheduled Y) For review of each protocol, the quorum of ethics committee should be at least one member from the following representation:

  1) Basic medical scientist

  2). Finishing

  3) Legal expert

  4) Lay person from the community

  5) Social scientist or representative of NGO or philosopher or ethicist or Theologian or similar person.

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Conduct of meetings

- At the beginning of each convened IEC meeting, the IEC chair or designee will ask the members if anyone has a financial or nonfinancial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The IEC chair or designer will announce that members with a conflict of interest must excuse themselves from deliberations and decision on that research protocol. Regular meetings shall be held at least quarterly.
- Research involving vulnerable populations (vulnerable to coercion or undue influence) will be placed on the agenda only when at least one individual (IEC member or independent consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or an independent consultant has been obtained).If expertise with a specific vulnerable population is needed but not available from the IEC members, an expert member will be obtained or the item will be scheduled for a later meeting when expertise is available.
- Secretary shall obtain signatures on confidentiality, conflict of

interest, agreement, attendance etc.

- Chairman will initiate the meeting and secretary shall discuss the minutes of the previous meetings of IEC as well as major issues / policies discussed in minutes of the other IEC and present the agenda for the current meeting.
- The IEC shall inform the investigators to attend the full board meeting related to their studies and clarify doubts if any.
- IEC completes the adequate review of the research studies submitted. The committees will review the new studies, amendments, annual/ continuing review of ongoing studies, any other documents and assess final report so fall research activities through a scheduled agenda.
- The decisions shall only be made at meetings where a quorum is present.
- Only IEC members who attend the meeting will participate in the decision. Decisions will be arrived at through consensus / unanimous opinion amongst the members of IEC.
- The decision making is thus concerned with the process of deliberating and finalizing decisions. IEC will approve when all participating members give consensus and quorum will be present, without quorum the decision cannot be made.

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After the meeting

• The secretary shall compile the proceedings of IEC meetings. The minutes of the meetings will be compiled and sent to the chairperson for review within 7 working days.

• Once finalized, the IEC meeting will be signed by member secretary and chairperson and shall be circulated to all 1EC members within 15 days

• The minutes of the IEC meeting will be ratified in the subsequent IEC meeting Secretary shall e mail the minutes of the meeting (MoM) to IEC members after obtaining approval from the chairman.

• Place the original version of the minutes in the minutes file and copy of the minutes shall be filed in the corresponding research protocol file

• A copy of the decision letter along with all project related correspondence shall be placed in the appropriate project files and communicated to investigators.

• The secretary shall communicate the IEC decision to the investigators in writing.

Review of Policy

• The chairman is authorized to make recommendations to the committee about changes in the policy.

• The policy will be reviewed every two years

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Ethical Guidelines for Research and Publications

Ethical principles for protecting study participants

The main principles of ethics in nursing research for protecting study participants are beneficence, respect for human dignity, justice and the right to privacy. The Institutional ethical committee of Choithram Hospital and ethical committee of Choithram College of Nursing will ensure the observance of these ethical principles while conducting the research in the institution.

Beneficence

Beneficence imposes a duty on researchers to minimize harm and maximize benefits. Establishing the positive risk benefit ratio, where the risk of the research should never exceed expected benefits for people from knowledge generated by the research activity. A potential risk of the research study must be carefully assessed, and participants are protected from any harmful effect of research activity.

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Respect for human dignity

Humans should be treated as autonomous agents, capable of controlling their actions. This principle of ethics emphasizes on the freedom of choice, where the participants have right to accept or reject to be part of the research study.

Justice

This ethical principle directs the researchers to abide by the participant's right of fair treatment and maintenance of privacy. The fair and nondiscriminatory selection of the participants such as any risk and benefit will be equally shared by study participants.

The right to privacy

Researchers should ensure that their research is not more intrusive than it needs to be, and that participants' privacy is maintained continuously. Participants have the right to expect that their data will be kept in strictest confidence.

Misconduct in Academic Research

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Misconduct in academic research implies fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research. It includes failure to follow an agreed protocol if and when this failure results in unreasonable risk or harm to persons or the environment. It does not include honest error or honest differences in interpretation or judgment in evaluating research methods or results, or misconduct unrelated to research processes.

Misconduct includes (and is not limited to) the following activities:

Plagiarism

Authors who present the words, data, or ideas of others with the implication that they own the same, without attribution in a form appropriate for the medium of presentation, are committing theft of intellectual property and may be guilty of plagiarism and thus of research misconduct. This statement applies to reviews and to methodological and background/historical sections of research papers as well as to original research results or interpretations. If there is a word-for-word copying beyond a short phrase or six or

seven words of someone else's text, that section should be enclosed in quotation marks or indented and referenced, at the location in the manuscript of the copied material, to the original source.

The work of others should be cited or credited, whether published or unpublished and whether it had been written work, an oral presentation, or material on a website. Each journal or publisher may specify the particular form of appropriate citation. One need not provide citations, however, in the case of well-established concepts that may be found in common text books or in the case of phrases which describe a commonly-used methodology.

To ensure that the thesis is free from plagiarism, it is essential to conduct a plagiarism check before submission. For this purpose, both online and offline plagiarism detection software are used, and the certificate confirming this has been attached to the thesis.

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Abuse of Intellectual Property Rights: Failure to observe legal norms regarding copyright and the moral rights of authors.

Misinterpretation: The deliberate attempt to represent falsely or unfairly the ideas or work of others, whether or not for personal gain or enhancement.

Fabrication and Fraud: The falsification or invention of qualifications, data, information or citations in any formal academic exercise.

Defamation: Failure to observe relevant legal norms governing libel and slander.

Personation: The situation where someone other than the person who has submitted any academic work has prepared (parts of) the work.

Sabotage: Acting to prevent others from completing their work. This includes stealing or cutting pages out of library books or otherwise damaging them; or willfully disrupting the experiments of others; or endangering institutional access to licensed research resources by willfully failing to observe their terms and conditions

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Use and Misuse of Data

Research integrity requires that reported conclusions are based on accurately recorded data or observations. It is considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions, including the purposeful withholding of information about confounding factors. A large background of negative results must be reported. Any intentional or reckless disregard for the truth in reporting observations may be considered to be an act of research misconduct.

Ownership of and Access to Data

Research data obtained in studies performed at the Institution by employees of the Institution are not the property of the researcher who generated or observed them or even of the principal investigator of the research group. They belong to the Institution, which can be held accountable for the integrity of the data even if the researchers have left the Institution. Another reason for the Institution claim to ownership of research data is that the Institution, not the individual researcher, is the grantee of sponsored research awards. Reasonable access to data, however, should normally not be denied to any member of the research

group in which the data was collected. If there is any possibility that a copyright or patent application might emerge from the group project, a written agreement within the group should specify the rights, if any, of each member of the group to the intellectual property.

Authorship and Other Publication Issues

Publication of research results is important as a means of communicating to the scholarly world so that readers may be informed of research results and other researchers may build on the reported findings. In fact, it is an ethical obligation for an investigator at the Institution to make research findings accessible, in a manner consistent with the relevant standards of publication. The reported data and methods should be sufficiently detailed so that other researchers could attempt to replicate the results. Publication should be timely but should not be hastened unduly if premature publication involves a risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations.

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a. Criteria for Authorship

Since academic work is informed by a multitude of sources offering concepts and information, it is essential to emphasize rightful acknowledgement in the presentation of ideas and the publication of manuscripts. Authorship should be awarded only to those persons who have made an original and significant contribution to the conceptualization, design, execution and interpretation of the published work.

Individuals who have made smaller contributions by for instance giving advice, performing analyses or providing subject material, or who have supported there search in some other way, should also be acknowledged. The principal author should determine whether or not these individuals should be included as authors. Sometimes written permission has to be obtained for acknowledgement in the published work and even the format thereof is prescribed by the party concerned.

In the case of co-authorship, questions arise as to the criteria for inclusion as author, the ability of each author to evaluate all aspects of the study and the sequence of the list of authors. Authors should discuss these questions openly and should make appointments before undertaking a co-author project. The author submitting the work, or the principal author, is responsible for

coordinating the completion and submission ofthe work and for ensuring that all the contributions and all the collaborators are given proper acknowledgement. All authors should approve the final version of the manuscript and should be prepared to accept responsibility for the work in public.

Each author or co-author is responsible for the compilation, revision and verification of those parts of the manuscript, publication or presentation representing his/her contribution. All co- authors are entitled to making their own copies thereof, including figures and attached documents.

In factual or scientific reports, authors should go out of their way to quote applicable data, including those data not supporting the hypothesis proposed. It is the responsibility of the author(s) to be *au fait* with other appropriate publications and to quote from them.

It is unethical, and harmful to the academy, to present as one's own the work of others, whether in part or in full, to fabricate research results or to omit or change information.

Authors who wish to quote information obtained at a personal level or from unpublished written material should obtain written permission from the source.

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It is inappropriate and unacceptable to submit extracts from research, or reports on the same research, to more than one publisher, unless such action has been approved by the editors of each publication or multiple submissions is the acceptable standard practice in the specific discipline or field. In the complete report on the work in question, reference should be made to preliminary extracts from work that has already been published.

Order of Authors

Customs regarding the order in which co-authors' name(s) appear vary with the discipline. Whatever the discipline, it is important that all co-authors understand the basis for assigning an order of names and agree in advance to the assignments.

A corresponding, or senior author (usually the first or last of the listed names in a multi- authored manuscript) should be designated for every paper, who will be responsible for communicating with the publisher or editor, for informing all co-authors of the status of review and publication, and for ensuring that all listed authors have approved the submitted version of the manuscript. This person has a greater responsibility than other co-authors to vouch for the integrity of the research report and should

make every effort to understand and defend every element of the reported research.

Self-citations

In citing one's own unpublished work, an author must be careful not to imply an unwarranted status of a manuscript. A paper should not be listed as submitted, in anticipation of expected submission. A paper should not be listed as accepted for publication or in press unless the author has received galley proof or page proof or has received a letter from an editor or publisher stating that publication has been approved, subject perhaps only to copy-editing.

Duplicate Publication

Researchers should not publish the same article in two different places without very good reason to do so, unless appropriate citation is made in the later publication to the earlier one, and unless the editor is explicitly informed. The same rule applies to abstracts. If there is unexplained duplication of publication without citation, sometimes referred to as self-plagiarism, a reader may he deceived as to the amount of original research data.

It is improper in most fields to allow the same manuscript to he under review by more than one journal at the same time. Very atm

journals specify that a submitted work should not have been published or submitted for publication elsewhere, and some journals require that a submitted manuscript he accompanied by a statement to that effect.

An author should not divide a research paper that is a self-contained integral whole into a number of smaller papers merely for the sake of expanding the number of items in the author's bibliography.