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Dr. D. Y. Patil College of Nursing

Pimpri, Pune-18

INSTITUTIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES (SOP)

AUGUST 2023

VERSION-I

INSTITUTIONAL ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

(SOP)

Prepared by: Dr D Y Patil College of Nursing Pune

Reviewed by: Dr D Y Patil Vidyapeeth Pune

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Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

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Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

TERMS OF SOP

1. PURPOSE AND SCOPE OF THE PROPOSED EC:

i. To ensure a competent review of all ethical aspects of the project proposals received by committee

ii. To ensure the competent review and evaluation of all scientific and ethical aspects of research projects received in compliance with the appropriate laws, and welfare of participants.

iii. Consultations for clinical science and ethics.

iv. Education of professional, administrative, and support staff about ethical issues.

v. Creation, development, revision and implementation of guidelines for the IECs.

vi. Initiate research studies in ethics.

vii. Continuing education and training programs to ensure that IEC members are qualified to per- form their specific duties.

viii. To ensure quality and technical excellence and consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines 2017 and New Drugs and Clinical Trials Rules 2019

ix. To protect the rights of human subjects participants. To ensure the scientific validity and credibility of the data collected in human clinical studies.

x. To protect the dignity, rights and well being of research participants.

xi. To ensure that universal ethical values and international scientific standards are followed.

xii. To assist in the development and the education of a research community responsive to local health care requirements

xiii. The researcher should submit an appropriate application to the IEC along with the study protocol.

xiv. The IEC should be able to provide complete and adequate review of the research proposals submitted to them.

xv. All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained. Overview of ICH-GCP guidelines

xvi. The IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, should comply with GCP and with the applicable regulatory requirement(s), should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present, may invite non members with expertise in special areas for assistance.

xvii. Risks to study participants are minimized , Risks are reasonable in relation to anticipated benefits, Selection of study participants is equitable, Informed consent is obtained and appropriately documented for each participant, Adequate provisions for monitoring data collection to ensure safety of the study participants, Participant privacy and confidentiality is protected .

xviii. Conducting initial review , Conducting continuing review , Notifying the investigators about IRB decisions , Determining which studies require review more often than annually , Review and approval of changes in research activities , Determining which device studies pose significant or non-significant risk .

xix. Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards , Ensuring prompt reporting to appropriate institutional officials, regulatory agencies and funding sources of: unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with federal regulations, suspension or termination of IRB approval .

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

2. TYPES OF PROJECTS THAT WILL BE REVIEWED:

2.(A). i. All research projects involving human subjects (including any biological samples and behavioral issues) will be conducted at the Institute, irrespective of the funding agency or when no external funding agency is supporting the research.

ii. All research involving human participants requires ethical approval.

iii. It is necessary for all research proposals on biomedical, social and behavioural science research for health involving human participants, data to be reviewed and approved by an appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants.

iv. The head of the institution should appoint all EC members, including the Chairperson.

v. Every EC should have written SOPs according to which the committee should function. The EC can refer to ICMR guidelines in preparing the SOPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority. The SOPs should be updated periodically to reflect changing requirements. A copy of the latest version of SOPs should be made available to each member and they should be trained on the SOPs. The SOPs must be available in the secretariat of the EC as both hard and soft copies.

vi. The scope, tenure and renewal policy of the EC should be stated.

vii. Members of the EC should not have any known record of misconduct.

viii. The EC should be registered with the relevant regulatory authorities, for example, ECs approving clinical trials under the ambit of Drugs and Cosmetics Act should be registered with CDSCO.

ix. EC members will be given a reasonable honorarium for attendance at the meeting INR Rs. 1000/-

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

2. (B) Every EC member must:

- **i.** Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
- **ii.** Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
- **iii.** be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
- **iv.** be aware of relevant guidelines and regulations;
- **v.** Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
- **vi.** Sign a confidentiality and conflict of interest agreement/s;
- **vii.** be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
- **viii.** be committed and understanding to the need for research and for imparting protection to research participants in research.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

3. GENERAL PRINCIPLES

i. Research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value.

ii. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities.

iii. Therefore, protection of participants should be built into the design of the study. Do no harm (non-maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world.

iv. While conducting biomedical and health research, the four basic ethical principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants.

v. These four basic principles have been expanded into 12 general principles described below, and are to be applied to all biomedical, social and behavioral science research for health involving human participants, their biological material and data.

v. ***a) Principle of essentiality*** *whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee (EC) independent of the proposed research.*

v. ***b) Principle of voluntariness*** *whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded.*

v. ***c) Principle of non-exploitation*** *whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.*

v. ***d) Principle of social responsibility*** *whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.*

*v. e) **Principle of ensuring privacy and confidentiality** whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access*

*v. f) **Statement of General Principles** is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.*

*v. g) **Principle of risk minimization** whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.*

*v. h) **Principle of professional competence** whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.*

*v. i) **Principle of maximization of benefit** whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.*

*v. j) **Principle of institutional arrangements** whereby institutions where the research is being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.*

*v. k) **Principle of transparency and accountability** whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records,*

data and notes should be retained for the required period for possible external scrutiny/ audit.

v. l) Principle of totality of responsibility *whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly. Principle of environmental protection whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.*

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

4. MEMBERSHIPS REQUIREMENTS OF THE ETHICS COMMITTEE

i. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.

ii. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.

iii. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications.

iv. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

4 (a) CHAIRPERSON/ VICE CHAIRPERSON (OPTIONAL) NON-AFFILIATED

Qualifications -

A well-respected person from any background with prior experience of having served / serving in an EC

4.(a).i. *Conduct EC meetings and be accountable for independent and efficient functioning of the committee.*

4.(a).ii. *Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations.*

4.(a).iii. *Ratify minutes of the previous meetings.*

4.(a).iv*. In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.*

4.(a).v. *Seek COI declaration from members and ensure quorum and fair decision making.*

4.(a).vi*. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data.*

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

4 (b) MEMBER SECRETARY/ ALTERNATE MEMBER SECRETARY (OPTIONAL) AFFILIATED

Qualifications –

4.(b).i. *Should be a staff member of the institution*

4.(b).ii. *Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. Should be able to devote adequate time to this activity which should be protected by the institution • Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review*

4.(b).iii. *Schedule EC meetings, prepare the agenda and minutes*

4.(b).iv*. Organize EC documentation, communication and archiving*

4.(b).v. *Ensure training of EC secretariat and EC members*

4.(b).vi. *Ensure SOPs are updated as and when required*

4.(b).vii. *Ensure adherence of EC functioning to the SOPs*

4.(b).viii. *Prepare for and respond to audits and inspections*

4.(b).ix*. Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.*

4.(b).x*. Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.*

4.(b).xi. *Ensure quorum during the meeting and record discussions and decisions.*

4 (c) BASIC MEDICAL SCIENTIST(S) AFFILIATED / NON-AFFILIATED

Qualifications –

4.(c).i. *Non-medical or medical person with qualifications in basic medical sciences*

4.(c).ii*. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report*

4.(c).iii. *For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.*

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

4 (d) CLINICIAN(S) AFFILIATED/ NON-AFFILIATED

Qualifications –

4(d) i. Should be individual/s with recognized medical qualification, expertise and training

4(d) ii Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)

4(d) iii Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.

4(d) iv Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

4 (e) LEGAL EXPERT/S AFFILIATED/ NON-AFFILIATED

Qualifications –

4(e) i. Should have a basic degree in Law from a recognized university, with experience

4(e) ii. Desirable: Training in medical law.

4(e)iii. Ethical review of the proposal, ICD along with translations, MOU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.

4(e) iv. Interpret and inform EC members about new regulations if any

4(f) SOCIAL SCIENTIST/ PHILOSOPHER/ ETHICIST/THEOLOGIAN AFFILIATED/ NON-AFFILIATED

Qualifications –

4(f) i. Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

4(f) ii. Ethical review of the proposal, ICD along with the translations.

4(f)iii. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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4(f) iv. Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

4(g) LAY PERSON(S) NON-AFFILIATED

Qualifications –

4(g) i. Literate person from the public or community

4(g) ii. Has not pursued a medical science/ health related career in the last 5 years

4(g) iii. May be a representative of the community from which the participants are to be drawn

4(g) iv. Is aware of the local language, cultural and moral values of the community

4(g) v. Desirable: involved in social and community welfare activities

4(g) vi Ethical review of the proposal, ICD along with translation(s).

4(g) vii. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

4(g) viii. Serve as a patient/participant/ community representative and bring in ethical and societal concerns.

4(g) ix. Assess on societal aspects if any.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

5.CONDITIONS OF APPOINTMENT AND THE QUORUM REQUIRED

The head of the institution should appoint all EC members, including the Chairperson.

5 (a) CRITERIA FOR SELECTION OF MEMBERS OF AN EC

5 (a) i. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.

5(a) ii. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.

5(a) iii. The role of Chairperson / Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

5(a) iv. The appointment letter issued to all members should specify the TORs.

5(a) v. So as to maintain independence, the head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

5(a) vi. The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

5(a) vii. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

5(a) viii. The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.

5(a) ix. The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

5(a) x. As far as possible a separate scientific committee should priorly also review proposal before it is referred to EC. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

5 (b) MEMBERS OF THE EC COMMITTEE

Chairperson / Vice Chairperson (Optional)

5(b) i. Member Secretary

5(b) ii. Basic Medical Scientist(s)

5(b) iii. Clinician(s)

5(b) iv. Legal expert/s

5(b) v. Social scientist/ philosopher/ethicist/theologian

5(b) vi. Lay person(s)

5 (c) QUORUM REQUIREMENTS FOR EC MEETINGS

5(c) i. A minimum of five members present in the meeting room.

5 (c) ii. The quorum should include both medical, nonmedical or technical or/and non-technical members.*

5 (c) iii. Minimum one non-affiliated member should be part of the quorum.

5 (c) iv. Preferably the lay person should be part of the quorum.

5 (c) v. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

5 (c) vi. No decision is valid without fulfilment of the quorum.

**Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

5 (d) ROLE AND RESPONSIBILITY OF THE MEMBERS IN THE COMMITTEE

i. Chairperson / Vice Chairperson (Optional)

- Non-affiliated

Qualifications

- A well-respected person from any background with prior experience of having served/ serving in an EC

Responsibilities

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

ii. Member Secretary

- Affiliated

Qualifications

- Should be a staff member of the institution
- Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills
- Should be able to devote adequate time to this activity which should be protected by the institution

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

Responsibilities

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

iii. Basic Medical Scientist(S)

- Affiliated/ non-affiliated

Qualifications

- Non-medical or medical person with qualifications in basic medical sciences
- In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist

Responsibilities

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

iv. Clinician(S)

- Affiliated/ non-affiliated

Qualifications

- Should be individual/s with recognized medical qualification, expertise and training

Responsibilities

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

v) Legal Expert/S

- Affiliated/ non-affiliated

Qualifications

- Should have a basic degree in Law from a recognized university, with experience
- Desirable: Training in medical law.

Responsibilities

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

Vi) Social Scientist/ Philosopher/Ethicist/Theologian

- Affiliated/ non-affiliated

Qualifications -

- Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise
- Be sensitive to local cultural and moral values. Can be from an NGO

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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Responsibilities

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

vii) Lay Person(S)

- Non-affiliated

Qualifications

- Literate person from the public or community
- Has not pursued a medical science/ health related career in the last 5 years
- May be a representative of the community from which the participants are to be drawn
- Is aware of the local language, cultural and moral values of the community
- Desirable: involved in social and community welfare activities

Responsibilities

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

5(e) TENURE

- All members will be appointed for a period of Three (3) years.
- A defined percentage of EC members could be changed on a regular basis.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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6. PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS

The letter of resignation should be addressed to Head of institution and must be submitted to the Chairperson. Ethics committee then recommends it to the Head of institution. Members may also be disqualified from continuance in the following circumstances:

i. Absence for three consecutive meetings. (Both physical presence or technical review)

ii. Should the Chairperson provide written arguments to the (other) members and there is 2/3rd majority.

iii. Member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the job assigned)

iv. In case of Legal or Conflict of interest mis-conduct. Members that have resigned or have been disqualified may be replaced by Head of institution/ Officer-in-Charge.

v. **Resignation / Replacement procedure:** The members who have resigned may be replaced at the discretion of the appointing authority for the same. IEC members who decide to resign must provide the Head of institution and Chairperson, IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Head of institution would appoint a new member, falling in the same category of membership. The recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairperson.

vi. **Termination / Disqualification procedure:** A member may be relieved or terminated of his/her membership in case of Conduct unbecoming for a member of the Ethics Committee Inability to participate in the meetings on any grounds if a regular member fails to attend more than 3 meetings of IEC. The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Head of institution, by the Chairperson IEC for necessary action Relocate to another city or any such matter in all such situations/circumstances, Head of institution, will serve a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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the next duly constituted IEC meeting and IEC membership circular/ roster will be revised.

vii. The members who have resigned may be replaced at the discretion of the appointing authority for the same i.e., Head of institution who decide to resign must provide the Head of institution and Chairman, IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Head of institution, would appoint a new member, falling in the same category of membership. The recommendations may be sought from the resigning member.

viii. Appointment may be made in the consultation with Member Secretary and /or Chairman A member may be relieved or terminated of his/her membership in case of:

ix. Conduct unbecoming for a member of the Ethics Committee

x. Inability to participate in the meetings on any grounds

xi. If a regular member fails to attend more than 3 meetings of IEC.

xii. Relocate to another city or any such matter the membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Head of institution, by the Chairman IEC for necessary action.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

7. POLICY REGARDING TRAINING OF NEW AND EXISTING MEMBERS

i. New IEC members are required to undergo a training program on joining the Committee. It is the responsibility of the IEC Secretariat to give copy of the SOPs of the IEC, ICMR guidelines/stem cell research guidelines, etc to the IEC members for reference and use.

ii. The Member Secretary of the Ethics committee collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members. Formal training in Good Clinical Practice along with certification will be organized on regular intervals

iii. The Chairperson will identify the training requirements of the Committee members.

iv. The Chairperson and the Member Secretary will organize at least one workshop or training program for the Committee members every year.

v. The type of programs, areas for training and mentors for these workshops / training programs will be decided by the Chairperson in consultation with the Committee members.

vi. All relevant new guidelines should be brought to the attention of the members. b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record

vii. Ethics committee members should maintain competence by ensuring currency of their knowledge of:

vii. a) Good Clinical Practice (GCP) including Drugs and Cosmetics act., amended in 2019 ICMR-NIRRH Ethics Committee for Clinical

vii. b) Any changes in regulation

vii. c) Declaration of Helsinki and other International guidelines like CIOMS, WHO

vii. d) Ethical Issues

vii. e) National Ethical Guidelines for Biomedical Health Research involving Human Participants, ICMR, 2017

vii. f) E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH –GCP

vii. g) WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011

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vii. h) National guidelines for Stem Cell Research, ICMR, 2017

vii. i) National Ethical Guidelines for Bio-medical Research involving Children, ICMR, 2017

vii. j) Relevant laws and Regulations • International Issues/cases of Ethical concerns

vii. k) Developments in relevant science, technical and environmental, health and safety aspects

vii. l) Clinical audit procedures or monitoring practices. An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics will be attempted. Efforts would be made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

vii. m) Get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.

vii. n) Select the ones you need.

vii. o) Take approval from the IEC and the Head of institution

vii. p) Register to attend.

vii. q) Keep the receipt.

vii. r) Reimburse the training expense as approved by the Head of institution ICMR-NIRRH as per rules.

viii) Members should be trained in human research protection, EC functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

ix) EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented. Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members. EC members should be aware of local, social and cultural norms and emerging ethical issues.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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8.ROLES AND RESPONSIBILITIES OF THE EC

i. The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

ii. The EC must ensure ethical conduct of research by the investigator team.

iii. The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

iv. The EC 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 by attending meetings, participation in discussion and deliberations.

v. The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

vi. The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

vii. Responsibilities of members should be clearly defined. The SOPs should be given to EC members at the time of their appointment.

viii. The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

ix. The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

x. The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

xi. The EC should recommend appropriate compensation for research related injury, wherever required.

xii. The EC should carry out monitoring visits at study sites as and when needed.

xiii. The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

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Principal
Dr. D. Y. Patil College of Nursing
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xiv. The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

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Principal
Dr. D. Y. Patil College of Nursing
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9. PROPOSALS FROM OUTSIDE THE INSTITUTION

i. The EC is responsible for scientific and ethical review of research proposals. ECs 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 ethicatl compliance during the conduct of research. The EC should be competent and independent in its functioning.

ii. ECs should be multi-disciplinary and multi-sectoral.

iii. There should be adequate representation of age and gender.

iv. Preferably 50% of the members should be non-affiliated or from outside the institution.

v. The number of members in an EC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.

vi. The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

vii. The following requirements must be fulfilled by institutions that use the services of an EC from another institution:

vii .a) The two institutions (host & user) should enter into an MoU for utilizing the services of the EC of the host institutions or the user institution should provide a "No Objection Certificate" and agree to be overseen by the EC of the host institution.

vii .b) The EC of the host institution should have assess to all research record including the source documents and research participants for continuing review of the implemented project, including site visits.

vii .c) The EC of the host institution can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institutions.

Fees- Rs. 2000/-

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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9. (a). SUBMISSION AND REVIEW PROCEDURES:

Researchers should submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per EC SOPs.

9.(b). DETAILS OF DOCUMENTS TO BE SUBMITTED FOR EC REVIEW

- **i.** Cover letter to the Member Secretary
- **ii.** Type of review requested
- **iii.** Application form for initial review
- **iv.** The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable.
- **v.** Case record form/questionnaire
- **vi.** Recruitment procedures: advertisement, notices (if applicable)
- **vii.** Patient instruction card, diary, etc. (if applicable)
- **viii.** Investigator's brochure (as applicable for drug/biologicals/device trials)
- **ix.** Details of funding agency/sponsor and fund allocation (if applicable)
- **x.** Brief curriculum vitae of all the study researchers
- **xi.** A statement on COI, if any
- **xii.** GCP training certificate (preferably within 5 years) of investigators (clinical trials)
- **xiii.** Any other research ethics/other training evidence, if applicable as per EC SOP
- **xiv.** List of ongoing research studies undertaken by the principal investigator (if applicable)
- **xv.** Undertaking with signatures of investigators
- **xvi.** Regulatory permissions (as applicable)
- **xvii.** Relevant administrative approvals (such as HMSC approval for International trials)
- **xviii.** Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
- **xix.** MoU in case of studies involving collaboration with other institutions (if applicable)
- **xx.** Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable) Documentation of clinical trial registration (preferable)
- **xxi.** Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

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xxii. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

xxiii. Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)

xxiv. Protocol

9.(c). DETAILS OF DOCUMENTS TO BE INCLUDED IN THE PROTOCOL

The protocol should including the following:

i. The face page carrying the title of the proposal with signatures of the investigators;

ii. Brief summary/ lay summary;

iii. Background with rationale of why a human study is needed to answer the research question;

iv. Justification of inclusion/exclusion of vulnerable populations;

v. Clear research objectives and end points (if applicable);

vi. Eligibility criteria and participant recruitment procedures;

vii. Detailed description of the methodology of the proposed research, including

viii. Sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of Drugs, route of administration, duration of treatment and details of invasive procedures, if any; Duration of the study;

ix. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;

x. Procedure for seeking and obtaining informed consent with a sample of the atient/participant information sheet and informed consent forms in english and local languages. Av recording if applicable; informed consent for stored samples;

xi. Plan for statistical analysis of the study; Plan to maintain the privacy and confidentiality of the study participants;

xii. For research involving more than minimal risk, an account of management of risk or injury;

xiii. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;

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xiv. Provision of ancillary care for unrelated illness during the duration of research; an account of storage and maintenance of all data collected during the trial; and plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.

xv. Ethical considerations and safeguards for protection of participants.

9.(d). TYPES OF REVIEW EXEMPTION FROM REVIEW

Proposals with less than minimal risk where there are no linked identifiers, for Example, research conducted on data available in the public domain for systematic reviews or meta-analysis; observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; quality control and quality assurance audits in the institution; comparison of instructional techniques, curricula, or classroom management methods; consumer acceptance studies related to taste and food quality; and public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

9.(e). EXPEDITED REVIEW

Proposals that pose no more than minimal risk may undergo expedited review, for example; research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; research involving clinical documentation materials that are non-identifiable (data, documents, records); modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); revised proposals previously approved through expedited review, full review or continuing review of approved proposals; minor deviations from originally approved research causing no risk or minimal risk; progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review, research during emergencies and disasters.

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Principal
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9.(f). FULL COMMITTEE REVIEW

i. All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

ii. research involving vulnerable populations, even if the risk is minimal; research with minor increase over minimal risk; studies involving deception of participants; research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; major deviations and violations in the protocol; any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings.

iii. This may be decided by Member Secretary depending on the urgency and need; prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs. The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.

iv. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

v. Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.

vi. Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.

vii. EC members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review. All EC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs.

viii. The EC may adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees.

ix. The EC may have a system of appointing primary and secondary reviewers. The Member Secretary should identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.

x. The Member Secretary may identify subject experts to review the proposal as per need. These experts may be invited to the EC meeting or join via video/ tele-conference but will not participate in final decision making.

xi. The EC should meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.

xii. The designated (primary and secondary) reviewers and subject experts should conduct the initial review of the study protocol and study related documents as per the predefined study assessment form and for factors as described.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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10. ETHICAL ISSUES RELATED TO REVIEWING A PROTOCOL

i. **Social values**

a. The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society.

b. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.

ii. **Scientific design and conduct of the study**

a. Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit Although ECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy.

b. The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.

iii. **Benefit-risk assessment**

a. The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research.

b. Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.

c. The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures.

d. The EC should give advice regarding minimization of risk/ discomfort wherever applicable.

e. Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)

iv. Selection of the study population and recruitment of research participants

a. Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit.

b. Participants should be able to opt out at any time without their routine care being affected.

c. No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits.

d. Vulnerable groups may be recruited after proper justification is provided.

v. Payment for participation

a. Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed.

b. There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.

vi. Protection of research participants' privacy and confidentiality

a. ECs should examine the processes that are put in place to safeguard participants' privacy and confidentiality.

b. Research records to be filed separately than routine clinical records such as in a hospital setting.

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Principal
Dr. D. Y. Patil College of Nursing
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vii. Community considerations

a. The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs.
b. The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized.
c. Plans for communication of results to the community at the end of the study should be carefully reviewed.
d. It is important to examine how the benefits of the research will be disseminated to the community.

viii. Qualifications of researchers and adequacy assessment of study sites

a. The EC should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.

ix. Disclosure or declaration of potential Conflict-of-Interest (COI)

a. The EC should review any declaration of COI by a researcher and suggest ways to manage these.
b. The EC should manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.

x. Plans for medical management and compensation for study related injury

a. The proposed plan for tackling any medical injuries or emergencies should be reviewed.
b. Source and means for compensation for study related injury should be ascertained.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
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xi. Review of the informed consent process

The informed consent process must be reviewed keeping in mind the following:

a. the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations;
b. the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs; contents of the patient/participation information sheet including the local language translations (See section 5 for further details);
c. back translations of the informed consent document in English, wherever required;
d. provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and
e. if consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria. See section 5 for further details.

xii. Review of multicentric research

a. Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.
b. A large number of clinical trials, clinical studies and public health research including surveys are conducted at several research centres within the country or at international sites.
c. Multicentric research studies are carried out with the primary aim of providing a sound basis for the subsequent generalization of its results. All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.
d. There are concerns, however, related to duplication of effort in the parallel review by the involved ECs, wastage of time and also those related to communication between the committees.

xiii. Separate review by ECs of all participating site

a. The ECs/Secretariats of all participating sites should establish communication with one another. If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
b. The EC can suggest site-specific protocols and informed consent modifications as per local needs.
c. Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.
d. Common review for all participating sites in multicentric research
e. In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
f. This is especially important for research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
g. The meeting of the designated main EC can be attended by nominated members of ECs of the participating centres to discuss their concerns, if any, about ethics or human rights and to seek solutions and communicate the decision of the main

xiv. EC to their respective ECs.

a. This EC should be located in India and registered with the relevant authority (if applicable).
b. Meetings should be organized at the initial and, if required, intermediary stages of the study to ensure uniform procedures at all centres.
c. The site ECs, however, retain their rights to review any additional site specific requirements, ensure need-based protection of participants or make changes in the informed consent document (ICD), translations and monitoring research as per local requirements.

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Principal
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d. The protocol may be modified to suit local requirements and should be followed after it is duly approved by the EC of the host institutes/decision of main EC is accepted.

e. Adherence to protocols, including measures to terminate the participation of the erring local centres, if required should be monitored.

f. The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local participating sites would be required to obtain local ethical approval.

g. Sponsor/funding agencies should be informed about any site-specific changes being made, and the modified version should only be used by the concerned site.

h. Plans for manuscript publication and a common final report with contributors from the participating sites should be decided upon before initiation of the study.

i. Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

xv. Continuing review

a. Ongoing research should be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the SOP of the EC and at the time of according approval, and as indicated in the communication letter.

b. The EC should continually evaluate progress of ongoing proposals, review SAE reportsfrom all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.

c. Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs. The EC should also ensure compliance by the researcher. For academic and other trials, an institutional policy should be established.

d. The EC should examine the measures taken for medical management of SAEs. Participants should not have to bear costs for the management of study-related injury whether they are in the intervention arm or the control arm.

e. Compensation must be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable).

f. For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious the EC may halt the study. The EC may report to the institutional head/ government authorities where there is continuing non-compliance to ethical standards.

g. Reports of monitoring done by the sponsor and DSMB reports may also be sought.

xvi. Site monitoring

a. It is recommended that ECs should follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance or improve the function.

b. Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.

xvii. The following situations may justify "for cause" monitoring

a. high number of protocol violations/deviations; large number of proposals carried out at the study site or by the same researcher; large number of SAE reports; high recruitment rate; complaints received from participants; any adverse media report;

b. adverse information received from any other source; non-compliance with EC directions; misconduct by the researcher; and any other cause as decided by the EC.

xviii. Accepting proposals from outside the institution, mention the conditions of review & fee

a. It should not accept research proposals from investigators affiliated to institutions that have their own ECs unless there is an MoU.

11. SOP FOR VULNERABLE GROUP:

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

i. INDIVIDUALS MAY BE CONSIDERED TO BE VULNERABLE IF THEY ARE:

a. Socially, economically or politically disadvantaged and therefore susceptible to being exploited; incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled; able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

b. The key principle to be followed when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.

ii. PRINCIPLES OF RESEARCH AMONG VULNERABLE POPULATIONS

a. Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.

b. If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

c. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

d. In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.

e. Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

f. If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

iii. ADDITIONAL SAFEGUARDS/PROTECTION MECHANISMS

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate. Researchers must justify the inclusion of a vulnerable population in the research.

a. ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.
b. Additional safety measures should be strictly reviewed and approved by the ECs.
c. The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.
d. ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.
e. As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
f. Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
g. Research on sensitive issues such as mental health, sexual practices/preferences, HIV/AIDS, substance abuse, etc. may present special risks to research participants.
h. Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
i. Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.
j. Efforts should be made to set up support systems to deal with associated medical and social problems.

k. Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.

l. Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counselling centre.

v. OBLIGATIONS/DUTIES OF STAKEHOLDERS

All stakeholders have different responsibilities to protect vulnerable participants.

vi. STAKEHOLDERS OBLIGATIONS / DUTIES

Researchers

a. Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.

b. Justify inclusion/exclusion of vulnerable populations in the study.

c. COI issues must be addressed.

d. Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio.

e. Ensure that prospective participants are competent to give informed consent.

f. Take consent of the LAR when a prospective participant lacks the capacity to consent.

g. Respect dissent from the participant.

h. Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.

i. Research should be conducted within the purview of existing relevant guidelines/regulations.

vii. ETHICS COMMITTEES

a. During review, determine whether the prospective participants for a particular research are vulnerable.

b. Examine whether inclusion/exclusion of the vulnerable population is justified.

c. Ensure that COI do not increase harm or lessen benefits to the participants.

d. Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.

e. Suggest additional safeguards, such as more frequent review and monitoring, including site visits.

f. Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

g. ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.

h. ECs should have SOPs for handling proposals involving vulnerable populations.

viii. SPONSORS

a. The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.

b. The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC).

c. The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

ix. WOMEN IN SPECIAL SITUATIONS

a. Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons.

b. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomy of the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

x. REVIEW OF RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATION

a. Vulnerable persons are those individuals who are relatively or absolutely in capable of protecting their own interests and providing valid informed consent.

b. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

c. IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies

d. Additional safety measures should be strictly reviewed and approved by the IECs

e. IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable.

f. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witness after through explanation of risks and benefits.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

12. POLICY TO MONITOR OR PREVENT THE CONFLICT OF INTEREST ALONG WITH STANDARD OPERATING PROCEDURES

Conflict of interest (COI) is a set of conditions where professional judgement concerning

a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors.
ii. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.

a. Research institutions must develop and implement policies and procedures to identify, mitigate conflicts of interest and educate their staff about such conflicts.
b. Researchers must ensure that the documents submitted to the EC include a disclosure of of interests that may affect the research.
c. ECs must evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.
d. COI within the EC should be declared and managed in accordance with standard operating procedures (SOPs) of that EC.
e. The broad responsibilities of those involved in research, with respect to COI, are given below:

i. RESEARCH INSTITUTIONS MUST:

a) Develop policies and SOPs to address COI issues that are dynamic, transparent and actively communicated;
b) Implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies; Monitor the research or check research results for accuracy and objectivity; and Not interfere in the functioning and decision making of the EC.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

ii. RESEARCHERS MUST:

a) Ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research;

b) Guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and

c) Prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

iii. ECS MUST:

a) Evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this; and

b) Require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI; and

c) Make appropriate suggestions for management, if COI is detected at the institutional or researcher levels.

d) At the point of submission of manuscript for publication, research ethics dictate that each author reveal any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated - including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition.

e) If the manuscript is accepted, Conflict of Interest information will be communicated in a published statement.

Dr. Khurshid Jamadar
Principal
Dr. D. Y. Patil College of Nursing
Pimpri, PUNE - 18.

Dr. D. Y. Patil College of Nursing

Pimpri, Pune-18

Address : Sant Tukaram Nagar, Pimpri, Pune - 411 018. Maharashtra, India

E-mail : info.nursing@dpu.edu.in | **Website :** www.dpu.edu.in/www.nursing.dpu.edu.in