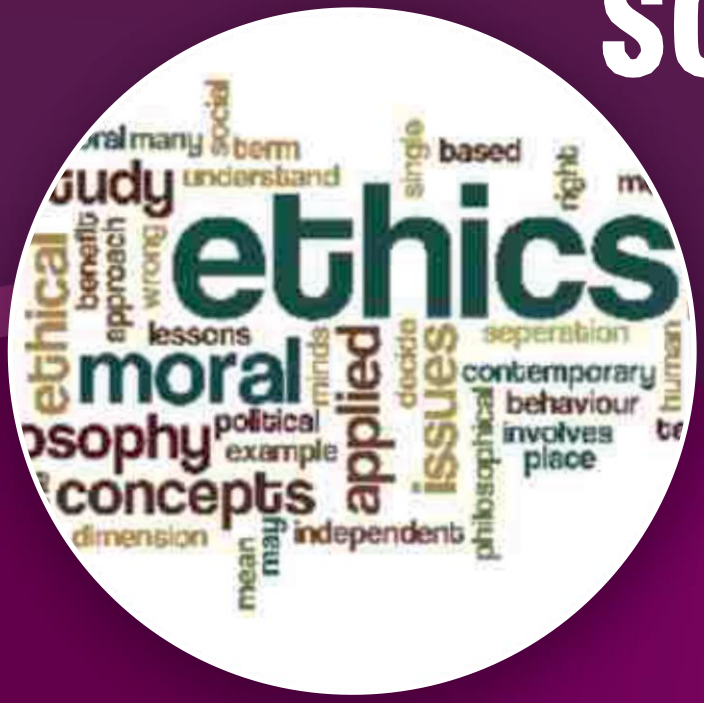
Dr. Vithalrao Vikhe Patil Foundation's

COLLEGE OF NURSING

INSTITUTIONAL ETHICS COMMITTEE SOP



principal@vimscon.edu.in | vimsineiec@gmail.com

www.vimscon.edu.in

Institutional Ethics Committee (IEC)

Dr.V.V.P.F's College of Nursing Ahilyanagar.

Title: Constitution of an Institutional Ethics Committee (IEC)

The location and business address of the committee :

Institutional Ethics Committee-CON, Ahilyanagar

Dr. Vithalrao Vikhe Patil Foundation's College of Nursing,

Opp. Govt Milk Dairy Vilad Ghat, MIDC Post

Dist : Ahilyanagar (Maharashtra)

Pin: 414111 India

SOP Code: SOP/01/V1.1

Effective Date : 01/08/2021

Date ofAmmendment : 01/08/2023

01/08/2025

Prepared By	Reviewed By	ApprovedBy
		
Ms. Rushali S. Kunjir (Clinical Instructor)	**Mr. Amol C. Temkar** (IQAC Coordinator)	**Dr. Pratibha A. Chandekar** (Principal)

TABLE OF CONTENTS

Term of Reference of the Committee

1. Introduction

With a population of over 1.3 billion and a high disease burden,1 India must engage in clinical research relevant to its healthcare needs to build evidence that drives policy. In India, the requirement for an ethical committee (EC) to oversee clinical research was first made in the Indian Council of Medical Research (ICMR) Policy Statement for Ethics published in 1982. Then came the Indian good clinical practices4 (GCP) in 2001 and the ICMR's Ethical Guidelines for Biomedical Research on Human Participants in 2006. The current guidelines were published in 2017 which are primarily a guidance document for medical, epidemiological, and public health research. One of the significant recommendations was a review by an appropriately constituted EC. The purpose of an EC in reviewing biomedical research is to safeguard the dignity, rights, safety, and well-being of all actual or potential research participants.

Research ethics committees review proposed studies with human participants to ensure that they conform to internationally and locally accepted ethical guidelines, monitor studies once they have begun, and, where relevant, take part in follow-up action and surveillance after the end of the research. Committees have the authority to approve, reject or stop studies or require modifications to research protocols. They may also perform other functions, such as setting policies or offering opinions on ongoing ethical issues in research.6 In general, any IEC's success depends on its members' commitment and devotion.

2. Purpose

The Institutional Ethics Committee (IEC) of the Dr. Vithalrao Vikhe Patil Foundation's College of Nursing, Ahilyanagar, in order to provide independent guidance, advice, and decision (in the form of "approval/recommendation/disapproval") on Nursing research comprising Clinical and public health, nursing education, nursing administration or other specific research protocols involving human subjects.

These standard operating procedures describe the Terms of Reference (TOR), which provide the framework for the constitution, responsibilities, and activities of Dr. V. V. P. F's College of Nursing Ethics Committee for clinical and public health studies. IEC will have both scientists and non-scientists, which are appointed by the Director/Officer-in-Charge. At least one-fourth of the IEC strength may be institutional, while the rest will be non-institutional members.

To function as an independent committee in its reflection, advice, and decision, the President /Officer-in-Charge will not be a member of the IEC; however, for the smooth functioning of the EC all the necessary infrastructure and facilities will be provided by the President /Officer-in-Charge.

1. To protect the dignity, rights, and wellbeing of the current and potential research participants.
2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

3. To assist in the development and the education of a research community responsive to local health care and nursing care requirements.
4. Promote responsible conduct of research and protect human subjects from potential risks.
5. Ensure compliance with national ethical and legal guidelines.

3. Scope of IEC:

1. To review the research proposals in an unbiased manner, without compromising the scientific quality, and ethical principles in conduct of biomedical, experimental and behavioral research.
2. To advise and educate the researchers on ethical guidelines in conducting research involving human participants.
3. To be updated with the relevant guidelines and regulations on research, research ethics, and good clinical practice.
4. To monitor the progress of approved research proposals with regard to compliance with protocol and ethical principles.
5. To review faculty and student research (UG,PG,PhD), community based research and surveys, collaborative or sponsored research, pilot studies and feasibility studies, internships or dissertations involving data from humans.

The SOP applies to the functioning of all activities under the IEC of Dr. V. V. P. F's College of Nursing. This includes the basic responsibilities of the IEC, composition, Appointment of the members, and conduct of the meeting.

4. Authority

The IEC derives its authority from the institution and operates independently. It reports to the **Head of the Institution (e.g., Principal/Dean)** and complies with the standards of the ICMR 2017 guidelines and any applicable legal regulations.

5. Functions & Responsibilities:

It is the responsibility of the IEC members, secretariat, and the Chairperson to read, understand and respect the rules set by the IEC of the Dr.V. V. P. F'S College of Nursing.

1. Review all research protocols for ethical compliance.
2. Ensure risk-benefit assessment, informed consent, privacy, and confidentiality.
3. Monitor ongoing research through periodic updates and site visits.
4. Handle protocol deviations, violations, and adverse event reports.
5. Maintain transparency, confidentiality, and documentation.
6. Educate and train researchers on ethics and Good Clinical Practices (GCP).

6. Meeting Frequency

- IEC shall meet at least **4 times a year** or more frequently as needed.
- **Quorum:** Minimum of 5 members must be present, including:
    - At least one external member
    - One lay person
    - One clinician or scientist

7. Decision-Making Process

Decisions shall be based on consensus. If consensus is not possible, a **majority vote** shall decide. Members with **conflict of interest** must declare and abstain from review of affected protocols.

8. Documentation & Record Keeping

As per ICMR 2017, the IEC shall maintain:

- Protocol submissions and decisions
- Meeting minutes
- Communication with investigators
- Annual reports and monitoring outcomes
- Records retained for **at least 5 years** post-completion or as mandated.

8. Confidentiality

All IEC members shall sign a **Confidentiality Agreement** and **Conflict of Interest Declaration** to maintain trust, data protection, and participant privacy.

9. Registration and Accreditation

The IEC shall be registered under the **National Ethics Committee Registry for Biomedical and Health Research (NECRBHR)** under the **Department of Health Research (DHR), Govt. of India**.

10. Amendments to ToR

Any changes to these Terms of Reference must be approved by the IEC and the Head of the Institution, in alignment with ICMR updates.

11.Activity Chart

SR.NO	Activity	Responsibility
1	Ethical basis	Institutional Ethics Commitee (IEC)
2	Composition of the Institutional Ethics Committee	Head of the Institute, Chairperson, IEC Members and Secretariat
3	Membership requirements	Head of the Institute, Chairperson,
4	Tenure of Membership	Chairperson, IEC Members and Secretariat
5	Policy statement of the institution &Appointment of new members and alternate members	Head of the Institute
6	Resignation and disqualification of members	IEC Members and Secretariat
7	Conditions of appointment	IEC Members and Secretariat
8	Training of the IEC Members in Research Ethics	IEC Chairperson Member Secretary
9	Selection and appointment of Chairperson, Member Secretary, Joint Member Secretary	Head of the Institute
10	Advisory committee/ Board	Head of the Institute Chairperson, IEC Members
11	IEC staff	Member Secretary
12	Quorum requirements	IEC Members and Secretariat
13	Honorarium to the Members/ Independent Consultants	IEC
14	Evaluation of !EC/Chairperson/Member Secretary/Members/Staff	HOI, IEC
15	Prepare an annual activity report for the IEC	IEC Secretariat
16	Prepare an annual activity report for the IEC	IEC Secretariat

12. Detailed Instructions

a. Ethical basis and Mandate

i. The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with national law and regulations.

ii. Institutional Ethics Committee (IEC) will review and approve all types of research proposals involving human participants with a view to safeguarding the dignity, rights, safety, and well-being of all actual and potential research participants. To ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner, the IEC may refer to the SOPs and Guidelines of the IEC-Dr. V. V. P. F'S College of Nursing.

iii. It will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

iv. It is a dictum that the goals of research, however important, should never be permitted to override the health and well-being of the research participants.

v. IEC should take up those proposals after ensuring the scientific soundness and technical appropriateness of the proposed research through the appropriate Scientific Review Committee or research committee of Dr. V. V. P. F'S College of Nursing.

vi. IEC will only review the research proposals basic research, genetic, socio-behavioural, action research, or operational studies in Nursing and Public health) which are conducted at the Institute. If the Principal Investigator at the Institute is undertaking a clinical, socio-behavioural/ operational, or basic research study, which is done in collaboration with a hospital/clinic/organization (of the government sector), which does not have an Ethics Committee, the IEC-Dr. V. V. P. F'S College of Nursing may offer its oversight on request and function as the EC for that hospital/ clinic. However, the hospital/ clinic must extend all cooperation to monitor the study's conduct.

vii. IEC is entrusted not only with the initial review of the proposed research proposals prior to initiation of the projects but also has a continuing responsibility of regular monitoring of the approved projects to foresee the compliance of the ethics during the period of the project. Such an on-going review shall be in accordance with international guidelines wherever applicable.

viii. IEC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IEC should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through Scientific Review Committee

b. Composition of the IEC

i. The IEC will have equal representation of both genders.

ii. To oversee the various researches undertaken at the society, the IECs should be multidisciplinary and multi-sectorial in composition with a minimum 7 and maximum 15 members to include members from various faculties such as basic, clinical, operational, statistics, general and social sciences.

iii. The external experts will include the specialties like clinical nurse specialists, nurse educationists, nurse administrators, biostatisticians, epidemiologists/socio-behavioral scientists, and legal advisors.

iv. Their expertise will be helpful while evaluating specific research studies addressed at the Institute. Thus, the IEC members should be a mix of medical/ non-medical, scientific, and non-scientific persons, including community persons, to help provide a patient's and public perspective and to represent the different points of view.

v. The Chairperson will not be affiliated with the Institute (Dr. V. V. P. F'S College of Nursing) to ensure the independence of the Committee. The Member Secretary will be from the same Institution and should conduct the business of the Committee.

vi. Though the decision will be by consensus, voting may be used (when consensus is not reached) for which a quorum of at least 5 is mandatory. No meeting will be considered valid if the quorum is not reached.

The composition may be as follows:

vii. Chairperson.

viii. Institutional members are to be included from various areas of expertise, such as clinical nurse specialists, nurse administrators, nurse educationists, and nurse specialists in public health.

ix. One - two persons from the basic medical science area.

x. Two or three clinicians from various Institutes/Hospitals/Medical Colleges.

xi. One legal expert.

xii. One - two social scientists/representatives of a non-governmental voluntary agency.

xiii. Two community members (who can voice out the concerns of the potential participants).

xiv. Member Secretary.

Alternate members:

xv. The IEC should nominate an alternate Chairperson who can be selected from the non-institutional IEC members. The alternate Chairperson can oversee/conduct the meeting in the absence of the Chairperson.

xvi. Considering the fact that there may be a conflict of interests when the Member Secretary is the Principal Investigator/ co-investigator or is absent from the meeting, the IEC may consider appointing an alternate Member Secretary who should be the institutional IEC member.

xvii. The alternate member of the required speciality (Legal Expert, Clinical expert, Community Member) can be selected for fulfilling the quorum in case the present member is not able to attend the meeting due to unprecedented prior commitments and the meeting is to be held on the same day.

xviii. Alternate members are suggested by the IEC and appointed by the President/Officer-in-Charge.

c. Membership requirements

i. In the interest of the Institute's research program, the IEC members, including the Chairperson and Member Secretary, will be selected by the President/ Officer-in-Charge taking into consideration their expertise, research interests, and experience in ethics.

ii. Selected members should possess the necessary research exprienence- scientific knowledge and expertise, knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IEC work.

iii. Committee members will be selected based on the basis that they are willing to publicize their full name, profession, and affiliation. Their Curriculum Vitiate should be submitted to the EC office for records.

iv. The Chairperson and the EC members should be informed of the potential members by the Member Secretary in the meeting, and their concurrence should be obtained.

v. Members must disclose in writing any interest or involvement - financial, professional, or otherwise - in a project or proposal under consideration.

vi. The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision.

vii. Members will be required to sign a confidential agreement at the start of their term. Dr. V. V. P. F'S College of Nursing Ethics Committee Members are appointed for a period of3 years, and the Member Secretary will serve the tenure for 5 years. On completing the tenure of the Member Secretary, he/she will be appointed as a member for a period of 6 months to ensure a smooth transition and the necessary help to the Member Secretary as per the decision of the President/Officer-In-Charge. The new member secretary should be an affiliated member for at least six months before taking up charge.

Their appointments may be renewed by the President/ Officer-in-Charge of Dr. V. V. P. F'S College of Nursing for up to two consecutive terms or as required by the President/ Officer-in-Charge.

ix. The Ethics Committee will include some rotation in the appointment of new members after a period of two years, but it will also strive to ensure continuity within the IEC. At no point in time will more than 25% of members be replaced.

x. For institutional Ethics Committee members, it is mandatory that the new members will act as observers for at least one meeting prior to their induction into the EC.

SN	Member	Responsibility
01	Chairperson	• Conduct EC meetings and ensure the active participation of all members during a meeting. • Ratify minutes of the previous meetings. • Seek declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for the use of EC data, etc.
02	Member Secretary	• Organize an effective and efficient procedure for receiving, preparing, circulating, and maintaining each proposal for review. • Schedule EC meetings, and 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 & adherence of EC functioning to the SOPs. • Prepare for and respond to audits and inspections. • Ensure completeness of the documentation at the time of receipt and timely inclusion in the agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, and invite independent consultants and patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
03	Medical Scientist	• Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology, statistics, the continuing review process, SAE, protocol deviation, progress and completion report, drug safety, and pharmacodynamics in case of clinical trials.
04	Clinician	• Scientific review 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 care, facility, and appropriateness of the principal investigator, provision for care, management, and compensation. • A thorough review of the protocol, investigators brochure & all other protocol details.
05	Legal Expert	• Ethical review of the proposal, ICD, translations, MoU, Clinical Trial Agreement, and regulatory approval. Insurance documents, other site approvals, researchers undertaking, protocol -specific permissions, compliance with guidelines, etc.
06	Social scientist	• Ethical review of the proposal, ICD, along with the trarnlations. • Assess the impact on community involvement, socio -cultural context, and religious or philosophical context, if any. • Serve as a patient/ participant/ societal/ community representative and bring in ethical and societal concerns.

07	Lay person	• Ethical review of the proposal. • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/ participant/ community representative and address ethical and societal concerns. • Assess societal aspects, if any.

SN	Member	Responsibility
02	Member Secretary	• Organize an effective and efficient procedure for receiving, preparing, circulating, and maintaining each proposal for review. • Schedule EC meetings, and 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 & adherence of EC functioning to the SOPs. • Prepare for and respond to audits and inspections. • Ensure completeness of the documentation at the time of receipt and timely inclusion in the agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, and invite independent consultants and patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
03	Medical Scientist	• Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology, statistics, the continuing review process, SAE, protocol deviation, progress and completion report, drug safety, and pharmacodynamics in case of clinical trials.
04	Clinician	• 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 care, facility, and appropriateness of the principal investigator, provision for care, management, and compensation. • A thorough review of the protocol, investigators brochure & all other protocol details.
05	Legal Expert	• Ethical review of the proposal, ICD, translations, MoU, Clinical Trial Agreement, and regulatory approval. Insurance documents, other site approvals, researchers undertaking, protocol -specific permissions, compliance with guidelines, etc.
06	Social scientist	• Ethical review of the proposal, ICD, along with the trarnlations. • Assess the impact on community involvement, socio -cultural context, and religious or philosophical context, if any. • Serve as a patient/ participant/ societal/ community representative and bring in ethical and societal concerns.
07	Lay person	• Ethical review of the proposal. • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/ participant/ community representative and address ethical and societal concerns. • Assess societal aspects, if any.

6.4 Tenure: Membership Duration

xi. The tenure for Members of the IEC is for a period of three (3) Years.

xii. There will be no bar on the members serving for more than one term, but it is desirable to have approximately one-third of fresh members.

xiii. A member can be replaced in the event of long-term non-availability (three consecutive meetings). The authority to replace the member shall remain with the Chairman.

xiv. Members should maintain the confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.

xv. Conflict of interest, if any, shall be declared by members of the Institutional Ethical Committee at the beginning of every meeting.

6.5 Resignation, Disqualification, Replacement of Members

To establish policies for the removal or Resignation / Replacement of members chairman and Member Secretary are responsible for implementing this SOP.

Term of appointment Members of the IEC will be appointed for a period of 3 years initially, which could be extended for another term of 2 years. Extension of membership will be based on the recommendation of the Chairman & Member Secretary of IEC.

Policy for removal of member

i. A member may be relieved or terminated of his/her membership in case of conduct unbecoming of a member of

ii. Inability to participate in the meetings on any grounds for more than 3 meetings of IEC.

iii. The Secretary general & chairperson shall review the membership if the member is a regular defaulter.

iv. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman IEC for nec

v. In all such situations/circumstances, the member secretary will serve a termination letter to the member.

vi. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeti will be revised.

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 Chairman & member secretary of IEC the written notificati 30 calendar days prior to the next scheduled meeting.
- In case of resignation, Chairman & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.

6.6 Independent Consultants

IEC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.

Independent Consultants are suggested by the Chairperson of the IEC in consultation with the Member Secretary and appointed by the President/Officer-in-Charge.

Their professional qualifications may be in community and/or patient representation or subject experts unique to the study proposal under ethics review. Subject experts could be invited to offer their views. It is desirable to include a member from specific patient groups in the Committee. Independent Consultants are appointed only for the review of the study sought. They will not be able to vote or be involved in decision-making.

- Independent Consultants may attend the meeting via teleconference or videoconferencing.

6.7 Conditions of Appointment

Chairperson, Member Secretary, Members, Alternate Chairperson, Alternate Members, and Independent Consultants are appointed to the IEC under the following conditions:

- Provide a recent CV (Naitik Portal format) and training certificate and good clinical practice (GCP) guidelines.
- Willingness to abide by the requirements laid in the SOP
- Read, understand accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time.
- Willingness to publicize his/her full name, profession, and affiliation.
- Willingness to undergo training or update skills/ knowledge during their tenure as an EC members.
- All financial accountability, reimbursement for work and expenses, if any, within or related to the IEC should be recorded and made available to the public upon request;
- All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.
- Be committed and understanding to the need for research and for imparting protection to research participants in research.

6.8 Officers and their responsibilities

The following officers, through their respective responsibilities, contribute to the good functioning of the IEC:

Chairperson:

He/ She is responsible for chairing the meetings and liaising directly with the President/Officer-in-Charge of the Institute, reporting the meeting outcomes to the President, invite independent consultants to provide special expertise to the EC on a proposed research protocol. He/ She should work in close coordination with the Member Secretary, review and sign along with the member secretary all the minutes and proposals and work towards the smooth function of the EC.

Alternate Chairperson:

He/ She is responsible for chairing the meetings in the absence of the Chairperson and acting as alternate Chair during meetings.

Member Secretary:

He/ She is responsible for the administrative aspect of the EC (see 6.9- below)

Alternate Member Secretary:

He/ She is responsible for the proceedings of the meeting in the absence of the member secretary/ if the member secretary has a conflict of interest for a study under review.

6.9 Secretariat

The Secretariat is composed of the Member Secretary and the supporting administrative staff, which includes a lower division clerk. It is mandatory that the clerical assistant ensure efficient record-keeping and retrieval of documents. The supporting staff is appointed by the President/Officer-in-Charge of the Institute.

The Secretariat shall have the following Functions:

- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance, and distribution of study files.
- Allocation of project reviews to specific members to facilitate efficient dispensation of the projects.
- Organizing IEC meetings regularly.
- Preparation and maintenance of meeting agenda and minutes.
- Receive and check for the completeness of the documents for review by the EC.
- Coordinate with the investigators for the translation (English-Hindi-Marathi) of the necessary documents.
- Arranging Community Members' meetings after the Board meeting for finalization of the Participant Information Sheet and Informed Consent Form. (Assent information sheet and assent form wherever applicable). This helps in making the documents lucid and in simple language, to make for easier decision-making by the Committee and reduces the considerable time of the Committee.

Maintaining the IEC's documentation and Archival

- Communicating with the IEC members and investigator applicants.
- Arrangement of training for personnel and IEC members.
- Organizing the preparation, review, revision, and distribution of SOP.
- Work in unison with the EC members and the investigators to reduce the turnaround time of the study proposals sent to the EC for review.
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature, to the Committee members.

6.10 Roles and Responsibilities of IEC members

- Regularly attend and actively participate in the EC meetings.
- Review, discuss, and consider research proposals submitted for evaluation. Reviewers for each proposal will review the study. Later, if there are any other issues, the other IEC members can voice their comments/suggestions.

- Discuss serious adverse event reports and recommend appropriate action(s). Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of IEC meetings. Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Conduct monitoring visits for any research proposal, if needed.

SN	Member	Responsibility
01	Chairperson	• Conduct EC meetings and ensure the active participation of all members during the meeting. • Ratify minutes of the previous meetings. • Seek declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for the use of EC data, etc.
02	Member Secretary	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review. • Schedule EC meetings, and 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 & adherence of EC functioning to the SOPs. • Prepare for and respond to audits and inspections. • Ensure completeness of the documentation at the time of receipt and timely inclusion in the agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, and invite independent consultants and patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
03	Medical Scientist	• Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology, statistics, the continuing review process, SAE, protocol deviation, progress and completion report, drug safety, and pharmacodynamics in case of clinical trials.

SN	Member	Responsibility
04	Clinician	• 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 care, facility, and appropriateness of the principal investigator, provision for care, management, and compensation. • A thorough review of the protocol, investigators brochure & all other protocol details.
05	Legal Expert	• Ethical review of the proposal, ICD, along with translatins, MoU, Clinical Trial Agreement, and regulatory approval. Insurance documents, other site approvals, researchers undertaking, protocol-specific permissions, compliance with guidelines, etc.
06	Social scientist	• Ethical review of the proposal, ICD, along with the translations. • Assess the impact on community involvement, socio-cultural context, and religious or philosophical context, if any • Serve as a patient participant/ societal/ community representative and bring ethical and societal concerns.
07	Lay person	• Ethical review of the proposal. • 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 societal aspects, if any.

6.11 Quorum Requirements

6.11.1 A minimum of five members, or one-third of the total members, must be present at a meeting beside Member Secretary and Chairperson in order to issue valid advice and/or decision, provided the quorum is met.

6.11.2 The quorum should include both medical, non-medical or technical or / and non-technical members.

6.11.3 Minimum one non-affiliated member should be a part of the quorum.

6.11.4 Preferably the lay person should be part of the quorum.

6.11.5 Professional qualifications of the quorum requirements should consist of the following:

- One legal expert.
- One Clinician.
- One socio-behavioral scientist/ one basic scientist depending on the projects to be discussed.
- At least one member who is independent of16 the institution/research site.
- At least one member whose primary area of expertise is in a non-scientific area, i.e., layperson or community member.
- The quorum of reviewing regulatory clinical trails should be in accordance with current CDSCO requirements.
- No decision is valid without fulfillment of the quorum.

6.12 Training of IEC members

All IEC members are conversant with Guidelines for Research involving Human Subjects. A team of trainers chosen for this purpose by Member Secretary will ensure that new members get trained within 30 days after being inducted. EC members are made aware of local, social and cultural norms of the society.

All IEC members will be made conversant with ICMR Guidelines for Research involving Human Subjects 2017, Cosmetics Act and ICH-GCP guidelines, human research protection, EC functions and SOPs. Any change in the relevant SOP or guidelines will be informed to the EC members periodically. Record of such training will be maintained in EC office.

6.13 Dissolving of the IEC

At any point in time, should the Institute cease to exist, the IEC is automatically dissolved. The IEC may also be dissolved at any time by the President/Officer-in-Charge of the Dr. V. V. P. F'S College of Nursing following written notification to each of the members.

13. SUBMISSION OF DOCUMENTS FOR IEC REVIEW:

a. Application Procedure

I. All proposals should be submitted in the prescribed application form, copies of which will be available to the Research Department.

11. All relevant documents should be enclosed with the application.

m. For projects within the University, no fee will be charged.

1v. For trials from outside agencies/sponsors, a fee of Rs 20000 is to be deposited along with the application form.

v. The required number of copies of the proposal (14 for ICMR and outside funded projects and for in-house projects as specified) along with the application and documents in the prescribed format duly signed by the PI and Co-investigators/ Collaborators should be forwarded by the Head of the Department.

v1. The Incharge Research Department will acknowledge the receipt and indicate any lacunae. Missing information should be replied to within two weeks or as specified.

v11. The date of the meeting will be intimated to the PI, which should be available to offer clarifications if necessary.

viii. The decision of the Institutional Ethical Committee will be communicated in writing. If a revision is to be made, the revised document in the required number of copies should be submitted within a stipulated period of time as specified in the communication.

b. Review of Projects:

I. Meetings of the Institutional Ethical Committee shall be held at scheduled intervals as prescribed. Additional meetings will be held as and when necessary. If there is no agenda, the meeting will be canceled, and Secretary will inform all members.

11. The proposals will be sent to members at least 2 weeks in advance.

111. Decisions will be taken by consensus after discussions, and voting will be done if necessary.

1v. Principle Investigator should be available during the meeting and will briefly present his proposal. He may be asked for any clarifications.

v. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.

v1. The decisions of the meeting shall be recorded in the form of minutes and shall be confirmed during the next meeting.

c. Element of Review of Proposed Projects:

1. Scientific design and conduct of the study.

11. Approval of scientific review committee/Research committee and other regulatory agencies.

m. Assessment of predictable risks & harms and potential benefits.

1v. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria, and other issues like sample size and advertisement details.

v. Management of research-related injuries, adverse events, and compensation provisions.

v1. Justification for placebo in the control arm, if any.

v11. Availability of products to the trial subjects after the study, if applicable.

viii. Patient information sheet and informed consent form in English/Hindi and local language.

1x. Protection of privacy and confidentiality of subjects.

x. Involvement of the community, wherever necessary.

x1. Protocol and proforma of the study, including the consent form.

xn. Plans for data analysis and reporting.

xiii. Adherence to Regulatory requirements and applicable guidelines.

xiv. Competence of investigators, research, and supporting staff.

xv. Facilities and infrastructure.

d. Review Process:

I. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

11. Only members will make the decision. The decisions shall be taken in the absence of Investigators, representatives of sponsors, and consultants.

111. The decision may be of approval, rejection, or recommendation to revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

1v. Revised proposals may be subjected to an expedited review.

v. All approved proposals will be subject to the laid down standard conditions. Additional conditions may be added by the Institutional Ethical Committee.

e. Expedited Review:

There is a specific provision for an expedited review of a study proposal/ amendment/ administrative matter; the procedure is followed on an expedited basis to arrive at a decision. Such an expedited review shall be at the discretion of the Chairperson and the Member Secretary, and for which the Sponsor shall pay the additional emergency fee as applicable.

The P.I. is advised to contact the Member Secretary to check whether or not the study proposal qualifies for an expedited review. The submission regarding expedited review should go through a review by the scientific advisory committee before sending it to the IEC chairperson and member secretary.

IEC will have the final authority to decide whether or not a study proposal should be accepted for expedited review.

Proposals that are recommended for minor revisions will be reviewed by a sub-committee appointed by the Institutional Ethical Committee (IEC) for clearance and approved by the Chairperson. The approvals will be reported in the next Institutional Ethical Committee meeting by Secretary. The revised form of proposals requiring major changes will be reviewed at the next IEC meeting. Rejected proposals may be reconsidered only if a very strong background is there.

7.5 Periodic updates to be submitted to IEC

1. All amendments in protocol/ INC/ IB or any new information available related to !EC-approved protocols must be submitted to IEC.

11. The investigator/Sponsor is responsible for supplying ongoing safety updates, progress reports (periodic) of trial status reports, and re-approvals (if required) to the IRB/IEC.

iii. P.I. is required to inform IEC in writing after the site is initiated.

1v. Half-yearly progress report to be submitted in the last week of every December and June. P.I.s are requested to submit 2 copies of each report to IEC, one to be given back to P.I., one for IEC record.

v. After receiving IEC approval, even if the site is not initiated half-yearly report must be submitted mentioning reasons for not initiating the site

v1. The P.I. will be required to intimate the name/s designation and nature of work/ responsibilities entrusted to all the members of his/her team in the said protocol. This information will have to be submitted by the P.I. along with the submission letter addressed to the Member Secretary. Change/sin such a job/responsibility profile will be immediately intimated to the Member secretary.

vii. If an assistant whose name is not intimated is entrusted with the said job/ responsibility, it will be considered a breach, and the IEC will take appropriate action in the matter, and this decision shall be final.

viii. The Principal Investigator and the said team shall abide by privacy and confidentiality when the study is approved by the IEC.

f. Communication of decision of Institutional Ethical Committee

1. The decision will be communicated to Principal Investigator by the Member Secretary in writing.

11. Suggestions for modifications and reasons for rejection shall also be communicated to the PI.

7.8 Reporting of Serious Adverse Event (SAE)

When a subject participating in the study develops any SAE or SUSAR, the PI must promptly report the incident to IEC as well as concerned authorities, including regulatory bodies, if applicable. The following are the rules at the College Of Nursing;

1. In the case of site-related serious adverse events, the Initial SAE report, along with a copy of the SAE form Appendix, is to be submitted within 24 hours.

11. If the adverse event was anticipated in the prot ocol and the subject was informed about the possibility of an event in the Informed Consent Form (ICF), there is no need to inform IEC unless the adverse event was unexpectedly serious, life-threatening, .Fatal.

111. If the adverse event was unanticipated, unexpectedly serious, life-threatening, or fatal, the adverse event must be reported to IEC through Member Secretary within 24 hours.

1v. If the study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must notify the regulatory authorities within 24 hours.

v. If the PI holds the "Investigational New Drug or Device" in his/her name, he/she is required to notify the regulatory authorities of the adverse event within 24 hours in addition to notifying to IEC.

v1. Notifying IEC does not relieve the PI from his/her responsibility to notify the sponsor or regulatory authorities.

v11. The PI must submit a written report of the adverse event or reaction to the IEC in the specified format within 10 working days.

viii. For industry-sponsored research, trials of drugs or devices, sponsors are required to inform investigators of adverse events that occur at other sites. When a PI receives such adverse forms from other sites, he/she must notify the IEC as early as possible.

1x. All the onsite SAEs will be reviewed by the "SAE Committee," which consists of one of the IEC members, a legal expert, and chairperson and member secretary. The committee will give detailed remarks on causal relations, compensation, risk benefits assessment, etc.

x. Final opinion regarding onsite SAEs will be sent to the licensing authority, duly signed by the chairperson, within 21 calendar days.

7.9 Follow-up

1. IEC will follow up on all studies which are cleared by it.

11. Investigators are required to submit a 6 monthly report to IEC apart from the final report.

111. Any AE, SAE, or Suspected Unexpected Serious Adverse Reaction (SUSAR) should be reported to IEC within 24 hours of the events.

1v. The IEC reserves the right to review the study or inspect the study site during the study period. The decision can be continuation, suspension, or termination of the study.

v. In case of premature suspension/termination of the study, the applicant must notify the IEC of the reasons for suspension/termination.

14. FINANCIAL MATTERS FOR IEC

a. Fees:

The committee may, after discussion with the Medical Director, decide upon/ announce/ change/amend/ alter, from time to time, announce and implement the fees for the Clinical Trial / Study / Protocol / Research Proposal. The said fees are payable by the Sponsors. The fees chargeable may be classified variously under heads such as protocol processing fees, per amendment/ follow-up study fees, and expedited review fees.

The processing fees are to be paid before approval of the protocol/amendment. An IEC approval letter will not be issued until a copy of the receipt of the processing fee is submitted to the Department of Research.

There will be no additional fee charged for the review and approval of the amended protocol and consent vers10n.

Fees charged for various types of documents.

Sr. No	Documents Type	Fees (Rs)
01	Academic studies (UG, PG, Faculty) In-house	Free
02	Review of New research proposal (Outside)	5000/-
03	Major amendment to a Sponsor based and IEC approved project (initiated by Sponsor) (Outside)	10000/-
04	Minor amendment to a sponsor based and IEC approved project (administrative changes only) (Outside)	5000/-

Mode of Payments:

Fees/Payments shall be paid by Cheque/DD drawn in favour of **DVVPF's College of Nursing, Ahilyanagar.**

Honorarium/ consultancy to the members/ invited experts will be paid as per the policy of Dr.V.V.P. Foundation Ahilyanagar.

15. For vulnerable population

As per ICMR- Guidelines for vulnerable population (page no 28 ICMR-Guidelines 2006)

Vulnerable groups: Efforts may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

1. Research on genetics should not lead to racial inequalities;

11. Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

m. The rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, the need for participation, the risks and benefits involved, and the privacy and confidentiality procedures. The entire consent process should be properly documented;

1v. Adequate justification is required for the involvement of participants, such as prisoners, students, subordinates, employees, service personnel, etc., who have reduced autonomy as research participants since the consent provided may be under duress or various other compelling reasons.

Full Review:

All research presenting with "more than minimum risk," proposals/ protocols which do not qualify for exempted or expedited review, and projects shall be subjected to full review by the EC.

I. Research involving vulnerable populations, even if the risk is minimal.

11. Research with minor increases over minimal risk.

iii. Studies involving the deception of participants.

iv. Research proposals that have received an 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.

v. Amendments of proposals/ related documents (including but not limited to informed consent documents, investigators broacher, advertisements, recruitment methods, case record forms, etc.) involving an altered risk.

v1. Major deviations and violations in the protocol.

v11. 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.

viii. Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need.

1x. Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

Review of research proposals involving vulnerable population:

Vulnerable persons are those individuals who are relatively or incapable of protecting their own interests and providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribal and marginalized communities; a refugees. Migrants, homeless, person or population 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.

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

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

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

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

15.1 ***Policy to monitor or prevent the conflict of interest along with standard operating Procedures:***

i. Conflict of interest, if any, is declared by members of the IEC at the beginning of every meeting.

ii. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

iii. Statement of conflicts of interest, if any, for PI

iv. HOD of the concerned department ensures that there should not be any conflict between different studies. Studies that are undertaken initially are finished first before undertaking another, which involves the same group of subjects.

v. The institutions shall establish and implement policies and procedures to identify, disclose, and mitigate conflicts of interest (COI), and ensure regular staff education on the same.

vi. Researchers must disclose any potential or actual conflicts of interest in all documents submitted to the Ethics Committee (EC)

vii. The EC reviews disclosed interests for each study and ensure that appropriate mitigation measures are implemented before approval.

Following are the responsibilities of those involved in research, with respect to COI :

1. **Research institutions must:**
   - Develop policies and SOPs to address COI issues that are dynamic, transparent and actively communicated;
   - 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.

2. Researchers must:

   - Ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research;
   - Guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and
   - 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.

3. ECs must:

   - Evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this; and
   - 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
   - Make appropriate suggestions for management, if COI is detected at the institutional or researchers level.

Following types of research cannot be collected without getting prior authorization:

i. Human participants and animals in research;
ii. Information posted on some websites;
iii. Hazardous materials and biological agents;
iv. Biological sample storage and future testing;
v. Information from some libraries, databases and archives;
vi. Published photographs and other published information; and
vii. Other copyrighted or patented processes or materials.

16. Glossary

Confidentiality: Prevention of disclosure, to other than authorized individuals, of IEC/IRB's information and documents

IEC: Institutional Ethics Committee is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection.

Scientists: Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

Consent form: An easily understandable written document that documents a potential participant's consent to be involved in research and describes the rights of an enrolled research participant. This form should communicate the following in a clear and respectful manner: research time frame; the title of research; researchers involved; the purpose of research; description of research; potential harms and benefits; treatment alternatives; statement of confidentiality; information and data to be collected; how long the data will be kept, how it will be stored and who can access it; any conflicts of interest; a statement of the participant's right to withdraw from participation at any point; declarative statement of understanding that the potential participant agrees to and signs. The consent form should be in a language the potential participant understands. For potential participants with limited literacy, verbal communication of the consent-document details should be provided along with proper documentation of consent if it is given.

Principal investigator (Pl): The main researcher overseeing or conducting the research process.

Research protocol: A document written by the investigator(s), which should contain a project summary; general information; background rationale; references and literature review; study goals and objectives; study design; methodology; safety considerations; follow-up; data management considerations and statistical analysis; quality assurance; expected outcomes of the study; dissemination of results and publication policy; duration of the project; problems anticipated; project management; ethical considerations; informed-consent documents; budge fun ding organizations; collaborations; curriculum vitae of each investigator; list of all current projects; duration and percentage of time spent on this project; any financing or insurance.

Research involving human participants: Any social science, a biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings:

1) Are exposed to manipulation, intervention, observation, or other interaction with investigators, either directly or through alteration of their environment; or

2) Become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records.

References

1. http://www.who.int/gho/countries/ind.pdf?ua=1
2. http://www.icmr.nic.in/bioethics/cc_biothics/presentations/int_chennai/CR_India.pdf.
3. http://www.dbtbiosafety.nic.in/Files/CD_IBSC/Files/Cosmetic.PDF.
4. http://www.cdsco.nic.in/html/GCP I.html.
5. http://www.cdsco.nic.in/html/D&C _Rules_pdf.
6. https://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
7. https://www.iitm.ac.in/downloads/ICMR_Ethical_Guidelines_ 2017.pdf 19

Annexure 1

Guidelines and codes of best practice:

Nuremberg Code 1: Established in 1947 in the aftermath of the Second World War to avert future atrocities in the name of science, the Nuremberg Code is a 10-point declaration framing key principles that have become the backbone of research ethics, including the following:

- Voluntary, informed consent
- Absence of coercion
- Opt-out possibility at any time during the experiment
- Scientific justification and necessity of the experiments
- Protection of the research subject against grievous bodily harm
- Proportionality of risk.

Declaration of Helsinki 2: The declaration was first adopted in 1964 by the World Medical Association, an international organization of physicians. There have since been six revisions, the last in the year 2008. Some of these revisions have been controversial, particularly with respect to the issues of placebo use in clinical trials and access to post-trial care. In addition to reiterating the principle of respect for research subjects, the Declaration of Helsinki underlines the importance of protecting vulnerable populations not capable of giving voluntary consent. Moreover, it stresses the obligation to offer the best proven care to trial participants after the end of the research project.

Unlike the Nuremberg Code, the Declaration 1 Available online at:

http ://ohsr.od.nih.gov/guidelines/nuremberg.html, accessed 17 January 2009. 2 Declaration of Helsinki, 6th revision (http://www.wma.net/e/policy/pdf/17c.pdf, accessed 17 January 2009).

Annexure 2

Policy statement of the institution

(On Letter head of Dr. V. V. P. F'S College of Nursing)

Date: _____ The Ethics Committees of Dr. V. V. P. F'S College of Nursing, known as the 'Institutional Ethics Committee (IEC) I will continue to review scientific and ethical aspects of all types of research studies involving human participants. It is resolved that IEC is constituted on __ and the new committee will serve for a 3 years term from ___ to ___ _

The IEC will work according to the Standard Operating Procedures (SOPs) which have been formulated for this purpose and are effective from _____The mandate will be:

a. To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.

b. To function independently without any interfer ence n the review and decision-making process from the Head of the Institute.

c. The IEC shall adhere to existing applicable rules & regulation for its formation and functioning which includes the registration of IEC, criteria for selection, tenure, resignation, schedule of meeting, reporting to regulatory authority and other administrative process.

d. The IEC will follow Ethical Guidelines for Biomedical Research on Human Participants by Dr. V. V. P. F'S College of Nursing. The Committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, nursing and health related ethical aspects of a proposed research project. The terms of reference regarding appointment of members and schedule of meetings will be as described in the SOPs formulated by the IEC. The list of members & alternate members who will serve on the IEC with effect from__ are as follows:

1.----------

2.----------

3.----------

4----------

5----------

6----------

7----------

Annexure 3

/EC Evaluation Form of Chairs & Co- chairs

1. Mention ( )the individual who is performing the evaluation:

Self-evaluation:

Supervisor or another administrator:

Member secretary IEC:

IEC members or other chairs or vice- chairs:

2. Name of the person who is evaluated:

3. Number of Meeting attended out of total meetings:

4. Number of exempt determinations made:

5. Number of protocols reviewed by the expedited procedure:

6. Number of protocols reviewed that went to the convened IEC:

7. Number of reviews completed as the primary reviewer:

8. Completion of educational requirements: Yes/No

9. Attendance at educational sessions (Make tick ( )in the column) Regular: Irregular:

10. Number of educational sessions conducted:

Evaluation of Chairs & Co- chairs

Person performing the evaluation- _____

Name of the person who is evaluated- _____

Period-

i) Preparedness for meetings Scale: Poor, Fair, Average, Good, Excellent

ii) Contribution to IEC meetings Scale: Poor, Fair, Average, Good, Excellent

iii) Quality of reviews Scale: Poor, Fair, Average, Good, Excellent

iv) Communication with IEC staff Scale: Poor, Fair,Average, Good, Excellent

Feedback

Signature: Date:

Note: (Poor,Fair,Average, Good, Excellent- 12 3 4 5)

Annexure 4

IEC Evaluation Form of IEC Member Secretary/Members

1. Mention ( )the individual who is performing the evaluation:

Self-evaluation:

Supervisor or another administrator:

Member secretary IEC:

IEC members or other chairs or vice- chairs:

2. Name of the person who is evaluated: _____

3. Number of Meeting attended out of total meetings:

4. Number of exempt determinations made:

5. Number of protocols reviewed by the expedited procedure:

6. Number of reviews completed as the primary reviewer:

7. Completion of required checklist: (Make tick( )in the column) Yes: No: ☐☐

8. Preparedness for meetings: (Make tick( )in the column) Good: Average: Poor: ☐☐☐

9. Contribution to IEC meetings: (Make tick ( )in the column) Good: Average: Poor: ☐☐☐

10. Quality of Reviews: (Make tick ( )in the column) Good: Average: Poor: ☐☐☐

Annexure 5:

List of the members of /EC

Name	Gender	Qualification	Role in the EC	Affiliation with the Institute

(Alternate members- these are invited only when the primary person is unable to attend the IEC Meeting]

Annexure 6:

Format For Approval Of Institutional Ethics Committee

Mr/Ms.

Principal Investigator

Dear, Mr/Ms. ----------

Ref: your letter dated----------

The Institutional Ethics Committee reviewed and discussed your application to review the Protoco1/amendment ICF entitled."

IEC has reviewed and approved in principle the above mentioned Protocol/ amendment/ ICF

The following below study-related documents have been reviewed in the meeting:

Sr. No	Submission Documents (For investigational site EC)	Version(s)/ Date of document

The following members of the Institutional Ethics Committee were present at the meeting held on date ---------- at time---------- at DVVPF, College of Nursing Ahilyanagar.

Names	*Qualification*	*Affiliations*	*IEC Designation & Role*	*Gender*

Please note that the Principal Investigator was invited to explain the protocol. He/She and/ or other study staff members did not participate in the decision making/ voting procedures.

Please note that this is "Approval in Principle "The study cannot be initiated unless final approval is issued. The Final approval will be issued after completing all the pending items/ documents as per regulatory requirements and IEC SOPs-

The Institutional Ethics Committee Dr.VVPF's College Of Nursing follows procedures that are in compliance with the requirements of ICH (international Conference on Harmonization) guidance related to GCP (Good Clinical Practice) and all applicable Indian regulations.

The Institutional Ethics Committee Dr.VVPF's College Of Nursing expects to be informed about the progress of the study mention frequency as per EC SOP, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely, **Date of lssue-**

Member Secretary OR Joint Member Secretary, IEC

Annexure 7:

Request Letter By Principal To The Members

From,

The Principal

Dr.VVPF's College Of Nursing,

Ahilyanagar

To,

Sub: Constitution of Institute Ethics Committee (Human studies)

Dear Sir

I am pleased to inform you that your name has been selected for the post of Chairman/ Member Secretary/ Member of IEC. Kindly send your written acceptance in enclosed format. On recipient of your acceptance, I shall send you the formal appointment letter.

Yours sincerely

Signature

Annexure 8:

Consent Letter By Members Of IEC

To

The Principal

Dr.VVPF's College of Nursing,

Ahilyanagar

Sub: Consent to be a member of Institute Ethics Committee (Human Studies)

Reg. Ref: You're Letter No:

Dear Sir,

In response to your letter stated above, I give my consent to become a Chairman/ Member Secretary/ Member of IEC of CON, Ahilyanagar. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.

Thanking you

Yours Sincerely

Signature

Name of the member

Department & designation

Date:

Dr.V.V.P. Foundations College of Nursing

Ahilyanagar

Project Proposal for Approval of Ethics Committee:

Summary Sheet

(NB: This is not supposed to be a detailed protocol of the study.)

Proposal Registration Number

Version No- 1

PART-A

1. Title:

2. Address/s of Institutions where the study will be undertaken :

3. Status of Review: ☐ **New** ☐ **Revised in compliance With IEC**

4. Investigators:

	Name	Designation	Dept.	Mobile	e-mail
PI					
Co-PI-1					
Co-PI-2					
Co-PI-3					
Co-PI-4					

5. Number of ongoing projects with PI (excluding this proposal) **As PI** ☐ **As Co-PI** ☐

6. Does the project require any additional / separate budget? ☐ **YES** ☐ **NO**

lfYES, give budget separately.

7. Study duration: **Years** **Months**

From(date) **To: (date)**

8. Aims & Objectives

9. Research Question/s

i.

ii.

iii.

12. Research Hypothesis (Where ever applicable)

i.

ii

iii

iv.

13. Population (Subjects) in whom study will be undertaken

Inclusion criteria	***Exclusion criteria***

14. Study Design: (Tick in appropriate cell)

Descriptive-Cross sectional		Descriptive Longitudinal
Cross sectional Analytical		Case-control study
Cohort study		Experimental drug trial (RCT)
Experimental :other than drug trial Viz: Trial of new surgical procedure		Phase: I/ II/ III/ IV
Animal study		
Evaluation of diagnostic test		Qualitative study
Any other (Specify)		

NB: For Drug trial I Experimental interventions like new surgical technique Appendix-D is mandatory

15. Variables to be studied/ measured (Mention main variables first and demographic and other variables later. Mention only those variables that you are actually going to analyze):

(Note: Measurement scale of variable include: Nominal, categorical, interval and ratio type. Measurement method may include questionnaire, interview, information from records or making actual measurement on/in patient. Measurement method may differ for different variables)

SNO	Variable name	Measurement scale	Measurement method
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

16. Sample size:

a. Assumptions for calculation:

1. Alpha(a)error(usually5%)
11. Beta( ) error (Usually 20%)
111. Variables assumed (Main variables in table at point No-10)
1v. Precision expected:
v. Design effect
v1. Hypothesis (wherever applicable): One sided/ two sided/ not applicable
v11. Any other (Specify)

b. Calculated minimum sample size:

c. Provision for loss to follow-up/ Attrition:

d. Total sample size (b+c)

17. Sampling method:

18. Expected outcome/s

11

111.

IV.

Part-B

19. Information about subjects included in the study

1. Type of special subjects if any in the study

Pregnant women		Fetus		Children
Lactating mothers		Elder persons		Handicapped
Terminally ill		Handicapped		MLCs
Mentally challenged		Others (Specify)		

1

1.

ii. Hospitalized/ OPD patients only ☐ Healthy individuals ☐

20. Mention if following tools will be used (with reasons if answer is NO)

Informed consent of subjects: YES ☐ NO
IfYES: Written ☐ Audio-visual ☐ IfNO; Reason:

11. Patient information brochure: YES ☐ NO ☐

Reason:

Patient Record Sheet: YES ☐ NO ☐

(NB: Patient record sheet is supposed to be different from the usual record of the patient like OPD/ IPD case paper. It is an important document supposed to be prepared especially for the purpose of study)

Reason:

111. Questionnaire/ Interview Proforma YES ☐ NO ☐ ***Reason:*** _____

21. Will the patients/ participants be required to bear any additional expenditure due to participation in the study? YES NO

If YES:

1. Approximate amount per participant

11. Is any financial provision made for this additional expenditure? YES/ NO

If YES: briefly explain the nature of provision.

22. Does the study involve use of:

SN	Use of	*YIN*	SN	Use of	*YIN*
1	Fetal tissue or abortus		5	Collection for banking/ future use	
2	Use or organ / body fluids		6	Ionizing radiation/ Radieoisotopes	
3	Use of recombinant gene therapy products		7	Use of infectious/ bio hazardous material	
4	Use of pre-existing stored samples		8	Sending samples abroad	

NB: For S. No-4; approval from Bhabha Atomic Research, Mumbai is required. For S.No 3, 7, 8 permission from Department of Bio-technology is required. If answer to any one of the above is YES; give details of collection, storage and transport

If answer to any of the above is YES; does it involve any risk to study participants?

23. Study end point (When will the study terminate?)

24. Mention probable benefits and risks to participants

Probable risks	Probable benefits

25. Privacy and confidentiality

1. Does the study involve: complete anonymity ☐

Direct identifiers ☐ indirect identifiers ☐

11. Confidential data handled by staff: Y/ N

111. Briefly mention the arrangements made to protect privacy and confidentiality

26. What are your plans of publication? (Mention the names of authors in sequence; PI should be first author)

Checklist for documents:

(Y =Yes, N=No, NA= Not applicable)

SN	Document	*YIN/* NA	SN	Document	*YIN/* NA
1	Undertaking by PI: Appendix A		9	Informed consent form	
2	CVs of PI and CO -Pis: Appendix B		10	Questionnaire/ Interview proforma	
3	Declaration of HOD/ HOI- Appendix C		11	MOU from sponsors**	
4	A Copy of detailed protocol as per format of IEC/MUHS/ICMR etc.		12	Permission from authorities like FDA, BARC etc	
5	Appendix *DIE* (For Experimental study only)		13	Insurance documents**	
6	Copy of advertisement for patient recruitment		14	Adverse event reporting protocol	
7	Patient record sheet		15	Patient information Brochure	
8	Budget Details				

Appendix-A

(Declaration cum undertaking by the principle investigator)

Proposal Title

Proposal Number

Name of PI

Designation **Department**

Institution

1. I undertake that I will initiate the project only after the clearance from the IEC of VIMS (herein after mentioned as IEC)
2. I declare that necessary permissions from participating departments in my institution and outside my institution have been taken.
3. I will not implement any deviations from protocol without prior approval of IEC
4. I declare that I am competent by way of qualification and experience to work as PI in this project.
5. I declare that all the CO-PIs in this study are competent by way of qualification and experience to work as CO-PI in this project.
6. I will personally supervise the project and will obtain all necessary legal and administrative permissions required for this project.
7. I will ensure complete and accurate recording in all documents related to the study.
8. I will inform in writing IEC within 24 hours about occurrence of any serious adverse event (SAE) and any un-expected adverse event (UAE) in this project.
9. I and my colleagues would respect the privacy and confidentiality of the information given by the participants in this study.
10. I will inform about the actual starting date of the project within 7 days of the start.
11. I would submit 6 monthly progress reports within 4 weeks of the completion of respective 6 moths.
12. I assure strict compliance with all legal and administrative procedures.
13. The information provided in the proposal is correct and accurate to the best of my knowledge and belief.

Signature

Name

Date Place

Appendix-B

(CVs of PI and CO-PIs)

Proposal Title

Proposal Number

(Use this sequence for PI and All Co-PI; add if required)

PI

Name

Designation Department

Institution

Qualification

Teaching experience (yrs): Asst. Professor Asso. Professor Professor

Research Experience in years: (as PG guide):

Publications in indexed journal: National International

Co-PI-1

Name

Designation Department

Institution

Qualification

Teaching experience: Asst. Professor Asso. Professor Professor

Research Experience:

Research Publications in indexed journal: National International

Co-PI-2

Name

Designation Department

Institution

Qualification

Teaching experience: Asst. Professor Asso. Professor Professor

Research Experience:

Publications in indexed journal: National International

Co-PI-3

Name

Designation Department

Institution

Qualification

Teaching experience: Asst. Professor Asso. Professor Professor

Research Experience:

Number of Publications in indexed journal: National International ------

Appendix-C

(Declaration by HOD/ HO/)

Proposal Title

Proposal Number

1. I certify that I have read the protocol of this project and I permit the study to be undertaken in my department/ Institution.
2. I assure of all administrative help required for the project which is within my administrative and financial powers.
3. I will report to IEC any Serious Adverse Event/ Un-expected adverse event within 24 hours if it comes to my notice.
4. I will report to IEC any major deviation in protocol of this project within 48 hours if it comes to my notice.

Signature of HOD

Name

Date

Place

Rubber Stamp:

(NB: A similar undertaking is required if the project requires help from other institution or if the study is multi-centric. It is advised to include as Co-PI at least one person from other department/ other institution if the project is inter-departmental/ multi-centric.)

Remarks of Head/ Principal of institution

Recommended / Not recommended (with reasons)

Signature of HOI / Principal

Name

Date

Place

Stamp:

Appendix-D

(Only for Experimental drug trial vaccine trial)

Study Title:

Name of PI

1. Is the study sponsored by any external agency?

YES/NO If YES; submit the copy of MOU to IEC

2. Is the drug you propose to try licensed for use by FDA for the condition/ disease under study ?

YES NO

3. Is the drug you propose to try licensed for use by FDA in the dose you propose?

YES NO

4. Is the drug you propose to try licensed for use by FDA by the route you propose?

YES NO

5. *Is the drug you propose to try licensed for use by* ***FDA in f****formulation your propose ?*

YES NO

6. If answer to any of the question number 2-5 is No: Is the permission from FDA authorities obtained?

(Reasons if answer is NO)

YES NO

Reason:

7. Have the safety studies for the drug in doses/ route and formulation you propose been done before?

Dose: YES NO

Route: YES NO

Formulation: YES NO

If answer to any of the above is YES: Attach references separately, If answer to any of the above is above question is NO; is your department/ institution capable/ competent to conduct such safety studies?

8. Mention known serious adverse events (SAE) of the drug/ interventions you propose to study from medical literature with its frequency range.

SAE	Incidence	SAE	Incidence
Mortality			

Appendix-D

(Only for Experimental drug trial vaccine trial)

9. Will the CONTROL group be deprived of any treatment during study period? (Placebo) YES/NO I/YES; give justification

10.1/it is a double blind trial; what is the protocol/or breaking the code in the event o/SAE?

11. Mention arrangements made for management of known SAEs

12. Mention arrangements like compensation/ insurance to the participants (in the event of SAE) made with documentary proof thereof.

Appendix-E

(Only for Trial of New Surgical Procedure/ Intervention)

1. Is the study sponsored by any external agency? ☐ YES ☐ NO

a. If YES; submit the copy of MOU to IEC

2. Does the study involve use of new instrument/ equipment? D YES ☐ NO

If YES: Give the details of FD Aapproval

3. Has the procedure/ intervention tried earlier elsewhere? ☐ YES ☐ NO

If YES: Give details

4. If answer to q-no 3 is YES: Give information about its safety and complications.

5. Give details of training received by PI/ CO-PI about the procedure/ intervention/ instrument

6. Have any pilot studies been done for the procedure/ intervention/ instrument? D YES D NO

If YES: Give details

Re-submission of Proposal

To

The Member Secretary

Dr.VVPF's College of Nursing IEC,

Ahilyanagar

Sub: Resubmission o/The Research Proposal

Ref: Project No

Titled:

Dear Sir

The aforesaid project was submitted to you/ IEC. It is here by resubmitted again with required corrections made as suggested. The corrected original proposal is enclosed herewith.

Signature of PI

Name of PI

Department

Institute

Re-submission of Proposal

Compliance Report

Project No

Project Title

PI:

Sr No	Comments of Research Cell/ IEC	Compliance	Compliance on Page No of the proposal

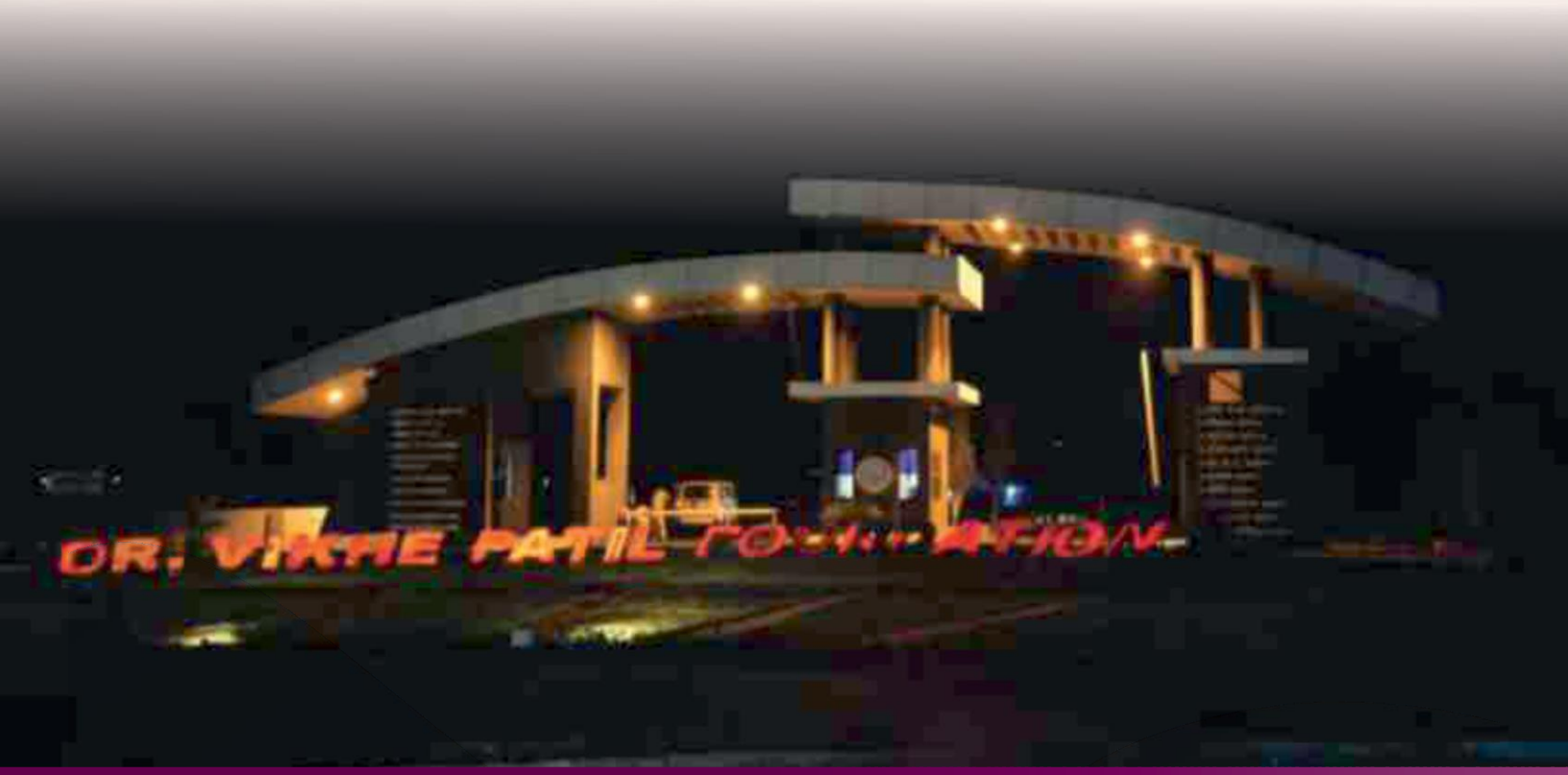
Signature of PI

Name of PI

Department

Institute

Dr. Vithalrao Vikhe Patil
Foundation
Ahilyanagar



DR. V.V.P.F's COLLEGE OF NURSING
AHILYANAGAR