IEC-VIMS

Dr. Vithalrao Vikhe Patil Foundation's Medical College and Hospital

Opp. Govt. Milk Diary, Post – Viladghat, Vadgaongupta, Ahmednagar (Ahilyanagar) - 414111

www.vims.edu.in

Document Name:	**Institutional Ethical Committee - Standard Operating Procedure**
Document No.:	**IEC-011**
No. Of pages:	**94**
Date created:	**07-03-2025**
Date of implementation:	**07-03-2025**
Prepared by:	Designation: IEC- Member Secretary Name: Dr. Kiran Vakade Signature: 7.3.2025
Approved by:	Designation: Dean Name: Dr. Sunil Natha Mhaske Signature: 07/03/2025

Member Secretary
I.E.C., V.I.M.S.
D.V.V.P.F's Medical College & Hospital
Ahmednagar

D.V.V.P.F's MEDICAL COLLEGE & HOSPITAL • AHILYANAGAR • DEAN

Responsibility of updating:	Designation: IEC - Member Secretary Name: Dr. Kiran Vakade Signature:

Member-Secretary
I.E.C., V.I.M.S.
D.V.V.P.F's Medical College & Hospital
Ahmednagar

DOCUMENT AMENDMENT RECORD

SL No	Section / Chapter	Revision Date	Description of the revision	Signature of the Chairman of the committee	Approved by Dean of the Institute
1.	The whole standard Operating Procedure (SOP)	7-3-2025	Updated as per ICMR rules and regulations		

CONTROL OF THE STANDARD OPERATING PROCEDURE OF IEC-VIMS:

- The holder of the copy of this Standard Operating Procedure is responsible for maintaining it in good and safe condition and readily identifiable and retrievable.
- The holder of the copy of this Manual shall maintain it in current status by inserting the latest amendments as and when the amended versions are received.
- The Institutional Ethical Committee Chairperson is responsible for issuing the amended copies to the copyholders, the copyholder should acknowledge the same and he /she should return the outdated copies to the Quality Manager.
- The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.
- The Standard Operating Procedure can be reviewed/updated as relevant to the institutional policies and procedures.
- This is a controlled document and must be issued in whole only. Do not make copies of this document.
- All information in this document is confidential and property of **DVVPF'S FOUNDATION's MEDICAL COLLEGE AND HOSPITAL, Ahmednagar (Ahilyanagar).**
- Reproduction of this document in any form, either in part or full to be done only with written permission of the Institution.

INDEX

1. PREPARATION OF STANDARD OPERATING PROCEDURES OF Institutional Ethics Committee- Vikhe patil Institute of Medical Sciences (IEC-VIMS)

1.1 Purpose:

- To define the process for writing, reviewing, distributing and amending SOPs of Institutional Ethics Committee- Vikhe patil Institute of Medical Sciences (IEC-VIMS).
- To ensure quality and consistency in review of research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.
- To ensure that the activities of Institutional Ethics Committee- Vikhe patil Institute of Medical Sciences (IEC-VIMS) are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines. Uniformity of the processes is ensured by SOPs.
- To provide existing and new joining members a training tool for the procedure by which SOP's shall be prepared, issued and revised.
- To maintain regulatory and legal compliance.

1.2 Scope:

Writing, verifying, reviewing, revising/amending and issuing the SOPs

1.3 Responsibilities:

The SOPs shall be reviewed and revised if required and notified in amendments. The Chairperson of IEC-VIMS appoints the teams for preparation/ revision of SOPs. The prepared SOPs are reviewed by all members of IEC-VIMS in a meeting. The Chairperson verifies and approves the SOPs.

1. 4. Procedure:

I. The Chairperson of IEC-VIMS appoints teams for preparation/revision of SOPs.

II. The team will have a leader and two or three members. The team leader should be the one who has thorough understanding of the ethical review process, evident by his/her experience and the training he/she has undergone. The leader will discuss with the team members and design the SOPs.

III. The draft of the SOP will be presented in the meeting of full committee. Suggestions or corrections from the members will be incorporated.

IV. The SOPs are reviewed by the Chairperson, the Member Secretary and a senior member of IEC-VIMS. The Chairperson will be the final approving authority for SOPs.

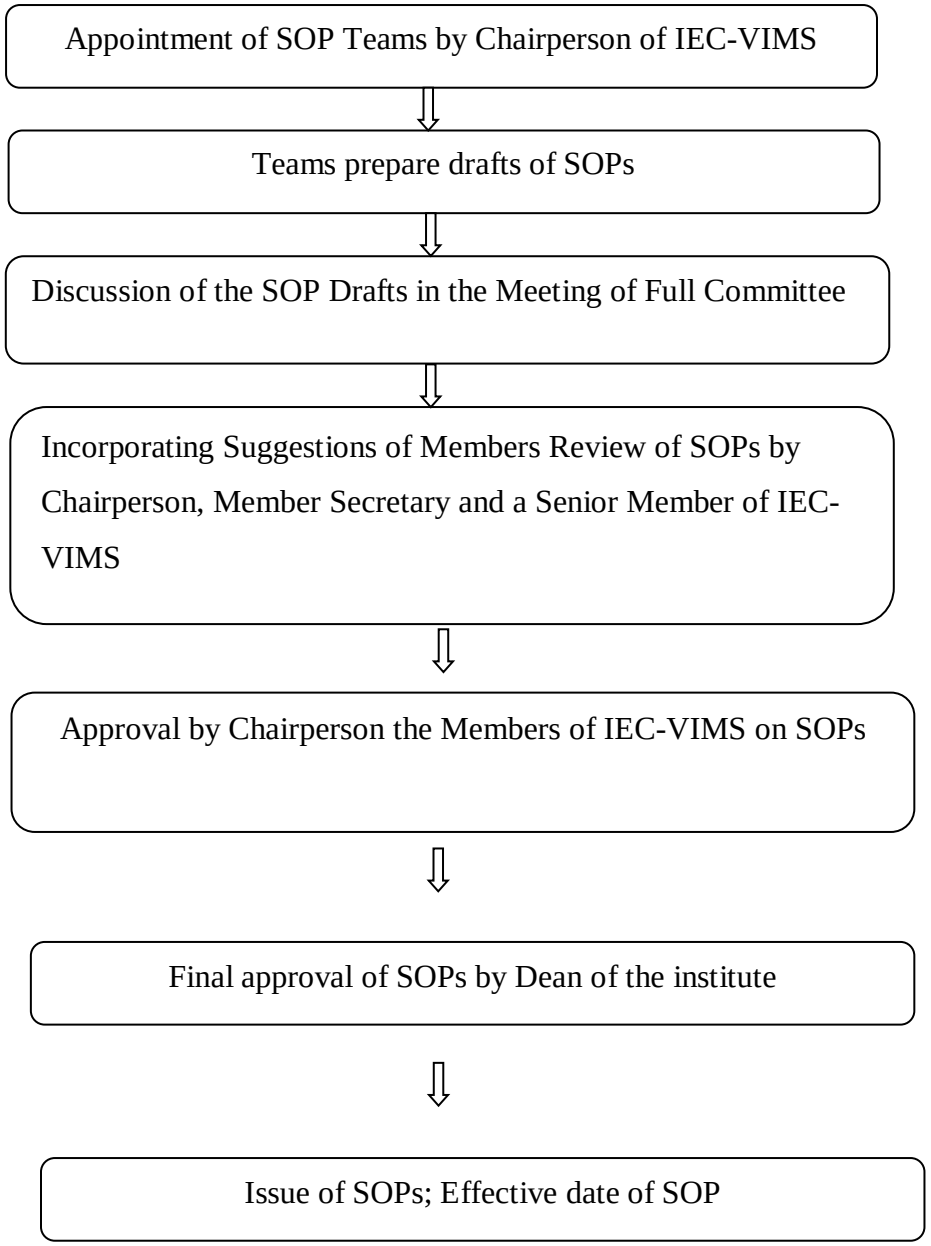
V. The new SOP is effective from the date of issue.

VI. When the revised SOP is made, it becomes the current version, and the previous version will be considered “obsolete”. The Member secretary will take back the “obsolete” version and then issue “current” version.

VII. If any changes are required in the SOP, due to any suggestions from members of IEC-VIMS, implementation of revised guidelines, etc., amendments will be made. The Chairperson will assess the need for amendment and authorize the Member Secretary to do the needed amendments.

VIII. Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by Member Secretary or authorized individual. A distribution log would be maintained.

1.5. Flow Chart: SOP Preparation



2. Objectives of SOP

The objective of this SOP is to maintain effective functioning of the IEC and 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 and New Drugs and Clinical Trials Rules 2019.

3. Authority under which IEC is constituted:

The IEC- VIMS is the ethics committee which functions independently. The Head of the institute (Dean) will appoint the chairperson and all the committee members based on qualifications, competence, and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of IEC members will be for 3 years or till further orders.

4. FUNCTIONS OF INSTITUTIONAL ETHICS COMMITTEE (IEC-VIMS)

- IEC-VIMS should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

- IEC-VIMS will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and wellbeing of the research subjects.

- The IEC-VIMS will ensure that all the fundamental principles of research ethics viz, Autonomy, Beneficence, Non-maleficence and Justice are taken care of in planning, conduct and reporting of a proposed study.

- It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required.
- It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc.
- The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

5. CONSTITUTION OF IEC-VIMS:

- **Purpose:**

  The purpose of this is to define and describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of members of IEC-VIMS, and the procedure for maintaining confidentiality of all activities and documents.

- **Scope:**

  This SOP is applicable to appointment of members of IEC-VIMS, defining their roles and responsibilities.

- **Responsibility:**

  The appointment of the members of IEC-VIMS will be done by the Dean of the institution. Every member is expected to follow this SOP.

- **Procedure:**

  The appointing authority for IEC-VIMS members is Dean of DVVPF's Foundation Medical College and Hospital.

- The Dean appoints the chairperson, the member secretary and other members of the committee.

- The Member Secretary sends an official request letter to the members who will confirm their acceptance to the Dean by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice. The Consent letter includes consent from the member, declaration of maintaining confidentiality of research project - related data/documents/ discussions, and willingness to get updated on research ethics, good clinical practice and regulations on human research. On receiving this consent, the Dean will issue the appointment order.

6. Composition of IEC-VIMS

The number of members in an IEC may range from 7 to 15. The IEC will be multidisciplinary in composition and independent.

As per ICMR guidelines Ethics committee membership typically requires a mix of individuals with scientific expertise and non-scientific backgrounds, including laypersons and legal experts. At least 50% members should be non-affiliated or from outside the institution, and the committee should have adequate representation of age and gender. Membership includes medical scientists, clinicians, legal experts, social scientists, philosophers, and laypersons from the community.

As per the ICMR National Ethical Guidelines2017, IEC-VIMS should have the following categories of members

I. Chairperson – None affiliated
II. Member Secretary- Affiliated
III. Basic medical scientist-Non-affiliated/affiliated
IV. Clinicians -Non-affiliated/affiliated

V. Legal expert -Non-affiliated/affiliated

VI. Social Scientist /representative of NGO/Philosopher//ethicist/theologian-Non-affiliated/affiliated

VII. Lay person from the community -Non-affiliated

The committee will be normally reconstituted every 3 years.

7. Criteria for selection of IEC-VIMS Members:

Sr.No.	EC member	Qualification
1	Chairperson Non-affiliated	✓ A well-respected person from any background with prior experience of having served/serving in an EC.
2	Member Secretary Affiliated	✓ 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.
3	Basic Medical Scientist(s) Affiliated / non-affiliated	✓ Non-medical or medical person with qualifications in basic medical sciences ✓ In case of IEC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.
4	Clinician(s) Affiliated/ non-affiliated	✓ Should be individual/s with recognized medical qualification, expertise and training.
5	Legal expert/s Affiliated/ non-affiliated	✓ Should have a basic degree in Law from a recognized university, with experience

		✓ Desirable: Training in medical law.
6	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated	✓ Should be an individual with social/behavioural 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
7	Lay person(s) Non-affiliated	✓ Literate person who has not pursued a medical science/ health related career in the last 5 years ✓ May be a representative of the community and aware of the local language, cultural and moral values of the community ✓ Desirable: involved in social and community welfare activities

- Generally, the term of EC membership is 3years.
- A defined percentage of EC members should be changed on a regular basis.
- All ethics committee members either be trained in human research protection and/or GCP at the time of induction into the EC. Institute should conduct such training sessions to train the newly appointed members.
- EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented.
- EC members should be aware of local, social and cultural norms and emerging ethical issues.
- 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.

- 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.

- 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.

- 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.

- 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.

- 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.

8. Requirements from Members when they give consent to be the members of IEC-VIMS

- The secretariat should collect a copy of recent curriculum vitae from all the members.
- The copies of degree certificates and medical council registration certificates should be collected from medical members of committee.
- In addition, certificates of training if any, in research methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC office.

9. Consent Letter and Confidentiality agreement from Members:

- When the members agree to be part of IEC-VIMS, they need to sign a consent letter in which they declare their commitment for all activities of the committee, and maintaining confidentiality of activities and documents of IEC-VIMS.
- The staff of secretariat of IEC-VIMS has to sign an agreement of maintaining confidentiality.
- Chairperson of IEC-VIMS will sign on all the confidentiality forms of members and secretariat staff.

10. Tenure of Membership:

The tenure of membership will be for a continuous period of 3 years from the date of appointment.

- **Appointment of New Members:**

New members will be appointed under following circumstances:

a) When a regular member completes his/her tenure

b) If a regular member resigns before the completion of the term

c) If a regular member ceases to be a member due to any reason such as death or disqualification

d) To fulfil the membership requirements as per SOP/guidelines/regulations

The new member will be identified by the Chairperson based on the membership requirements after discussion with the IEC. The name of new member to be appointed may be suggested by members of IEC. The Chairperson sends the proposal to Dean of the DVVPF's Foundation Medical College and Hospital. The final decision on appointment is taken by Dean.

- **Continuation of Membership after the Tenure:**

✓ The tenure of the members in the IEC-VIMS is three years. After the completion of three years, at least 1/3rd of the members will be replaced by new members.

✓ The replacement of a member will be done with new member of the same category (clinician/lay person/social scientist/philosopher, etc.).

- ✓ The decision on continuation of a member will be taken by the Dean of DVVPF's Foundation Medical College and Hospital. Opinion of Chairperson and Member Secretary may be taken into consideration in this process. A member can have maximum two continuous terms in IEC-VIMS. He/she may become a member again in IEC-VIMS after a gap of at least two years. The Dean will communicate to those who are replaced, acknowledging their service and contribution to the ethics committee.

- ✓ For the Chairperson and the Member Secretary replacements, same procedure will be followed. The Chairperson and Member secretary could get a second term after completion of the tenure. The Chairperson and Member Secretary can have maximum two consecutive terms.

- The Dean will send an appointment proposal letter to the members who will replace existing members, and also to the existing members who are going to continue.

- After obtaining consent, final appointment letter will be issued.

11. Conditions to be fulfilled by a member after appointment:

a) Members must submit a recent, signed CV
b) Members must submit training certificates in ethics and GCP (if available during induction)
c) Members should be ready to undergo training in ethical guidelines and GCP and submit the training certificates to the Member Secretary, IEC-VIMS.
d) Members must be willing to publicize his/her full name and affiliation.
e) Should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of IEC-VIMS.

12. Procedure for resignation, replacement or removal of the members

1. Resignation:

- ➢ Members can resign by submitting a written resignation letter to the Chairperson, which is then forwarded to the Head of the institute for further action.
- ➢ Resignation should be submitted at least 30 days before the next scheduled meeting.

- The Head of the institute will appoint a replacement in the same category of membership, and recommendations may be sought from the resigning member.

2. Replacement:

- In case of resignation, death, or long-term unavailability, the Head of the institute, in consultation with the Chairperson and Member Secretary, will appoint a replacement.
- The replacement should be from the same category of membership as the departing member.

3. Removal:

- A member may be relieved or terminated for reasons such as:
  - ✓ Conduct unbecoming for a member of the Ethics Committee.
  - ✓ If a member is incapable of performing his / her duty as a Committee member.
  - ✓ Inability to participate in meetings.
  - ✓ Excessive absenteeism (e.g., failing to attend more than 3 meetings).
- The IEC-VIMS may review the membership of a regular defaulter and recommend termination to the Head of the institute by the Chairman.
- The decision to remove a member is typically made by the IEC-VIMS and recommended to the Head of the institute.

13. Constitution of Subject Expert Panel: Selection, Roles and Responsibilities

- **Purpose**:

  The purpose of this is to define and describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of independent consultants, and the procedure for maintaining confidentiality of all activities and documents.

- **Scope :**

  This SOP is applicable to appointment of independent consultants of IEC-VIMS; defining their roles and responsibilities

- **Responsibility:**

The appointment of the members of subject expert panel (panel of independent consultants) for IEC-VIMS will be done by the Head of the Institution. The independent consultants need to maintain confidentiality of the reviews, meetings and documents.

- **Procedure :**
  - ✓ **Appointment:**

  - ➢ The Chairperson and the Member Secretary place a proposal to the Dean, DVVPF'S MEDICAL COLLEGE AND HOSPITAL for appointing independent consultants. Independent consultants are experts from various subjects for which experts are not available among regular members of IEC-VIMS.

  - ➢ The consultants could be affiliated or non-affiliated to DVVPF's Foundation Medical College and Hospital. The Dean, DVVPF'S MEDICAL COLLEGE AND HOSPITAL appoints independent consultants.

  - ➢ The Dean communicates to the consultants a proposal of appointment. The consultant will confirm their acceptance to the Dean by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice. The consent letter includes consent from the member, declaration of maintaining confidentiality of research project- related data/documents/discussions, and willingness to get updated on research ethics, good clinical practice and regulations on human research. On receiving this consent, Dean will issue the final appointment order. The list of independent consultants is maintained in the office of IEC-VIMS.

  - ✓ **Tenure**:

The tenure of appointment of an independent consultant is 3 years. The panel will be reviewed and revised every two years.

✓ **Consulting an Independent Consultant for Review:**

The Member Secretary in consultation with the Chairperson decides on sending a research proposal for review depending on the requirement.

✓ **The requirements are as follows:**

➢ If the research is from a specialty for which experts are not available in the IEC-VIMS, and there is need for expert opinion. The subject experts could be affiliated or non-affiliated. Preferably, subject non-affiliated experts are invited to review to avoid any bias or conflict of interest. The suggestion for requirement of expert may also come from the Chairperson or any member of IEC-VIMS who feels the necessity during review process.

➢ The Member Secretary requests the independent consultant to review the research proposal (expedited/full review as required). The review form and proposal copy along with all enclosed documents (budget form, questionnaire, proforma, informed consent documents, etc.). For the expedited review, the consultant is requested to do the review and submit the filled review form to the ethics committee secretariat within one week. This review will be placed before the full committee meeting for ratification.

➢ For full review, the consultant is requested to attend the meeting of IEC-VIMS. He/she should be present only during the presentation of that particular proposal which was reviewed by him/her. The opinion of the consultant is taken. However, the consultant does not have voting rights.

✓ **Requirements from Independent Consultants:**

➢ The secretariat should collect a copy of recent, signed curriculum vitae from the independent consultants. In addition, certificates of training if any, in research

methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC-VIMS office. The consultants should also sign a confidentiality agreement

- Conditions to be fulfilled by a consultant after appointment:

  a) Must submit a recent, signed CV

  b) Must submit training certificates in ethics and GCP (if available during induction)

  c) Members must be willing to publicize his/her full name and affiliation

  d) Should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of IEC-VIMS.

  e) Should declare "conflict of interest" whenever it exists

- Termination of Membership: The consultant is a member only for the review of specific research proposals. Any independent consultant found of professional misconduct will be terminated from the membership.

14. Membership Duration and Responsibilities

- The duration of the membership will be 3 years
- There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
- A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Dean.

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

- Conflict of interest if any shall be declared by members of the IEC-VIMS at the beginning of every meeting.

15. Quorum Requirements for IEC meetings

a) Minimum five members must be present to form the quorum.

b) The quorum should include both medical and non-medical members

c) Minimum one non-affiliated member must be a part of the quorum

d) Preferably the lay person should be part of the quorum

e) The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

f) No decision is valid without fulfilment of the quorum.

16. Convention and conduct of IEC meetings

- The Chairperson will conduct all meetings of the IEC-VIMS.

- In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting. The alternate or acting chairperson should have the powers of the chair person and should be non-affiliated person.

- The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

- In the absence of Member Secretary alternate Member Secretary among the members, will organize the IEC meeting.

- All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by Member Secretary the proposals will be circulated to the IEC members.

- The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals

17. Procedure for Training and Assessment of Members

- **Purpose:**

The purpose of this procedure is to describe requirements and methodology for training and performance assessment of the IEC-VIMS members and the Secretariat.

- **Scope**:

This procedure applies to all the IEC-VIMS members and the secretariat.

- **Responsibilities:**
  - ✓ It is the responsibility of the IEC-VIMS Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC-VIMS members and the secretariat. The Chairperson is responsible for assessment of all IEC-VIMS members and complete a self-assessment exercise at prescribed intervals.
  - ✓ As per ICMR guidelines, Members should be trained in human research protection, IEC-VIMS functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

- ✓ IEC-VIMS members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented.

- **Procedure**

1. Topics for training

I. IEC-VIMS members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of IEC-VIMS members
- Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialties
- SOPs of the IEC-VIMS

II. Secretariat should have knowledge and relevant skills for conducting the following activities:

- Knowledge about IEC-VIMS SOPs and also guidelines for submission
- Good communication skills – oral and written
- Maintenance of IEC-VIMS records – both soft and hard copy

2. Induction Training of new IEC-VIMS Members

I. Every time a new committee is constituted, the members must undergo initial training within one month on ethics in clinical research, good clinical practice, training in human research protection and SOPs. An individual selected as a new member of the IEC-VIMS will be required to attend one meeting as an 'Observe' before being inducted as a member of the IEC-VIMS. The Member Secretary will provide an introductory training to the new member. The member during

the observer period will not have voting rights, but will have to sign letter of confidentiality. Appointment of observer as member would be on discretion of Chairperson in consultation with members, following which the appointment letter would be issued to the member.

II. The newly inducted member will be encouraged to undergo training on good clinical practice, training on human research protection, bioethics and guidelines on clinical research. The authorities of DVVPF'S MEDICAL COLLEGE AND HOSPITAL may sponsor the member for such trainings.

III. The new member will receive trainings from any member of IEC-VIMS or Chairperson or Member Secretary on the above topics. An expert from clinical research, bioethics or Good Clinical Practice (GCP) will be invited to IEC-VIMS to give training

IV. The in house training sessions of IEC-VIMS will have pretest and posttest to assess the effectiveness of trainings.

V. The Member Secretary and the Chairperson will orient all the members on the SOP of the IEC-VIMS.

3. Ongoing (On Job and Developmental) Trainings at IEC-VIMS:

I. Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year. The authorities of the Institution may sponsor the members for such trainings.

II. The Member Secretary of IEC-VIMS in consultation with the Chairperson prepares an annual training schedule, and will conduct trainings or workshops on Good Clinical Practice, Bioethics, relevant guidelines on clinical research and

other relevant topics. The resource persons for such trainings could be a member of IEC-VIMS, or an external GCP trained personnel or a bioethics expert. The trainings are imparted not only to the IEC-VIMS members but, also to the institutional faculty who are investigators of ongoing research studies or potential investigators.

4. Training of the Secretariat:

- The IEC-VIMS Member Secretary along with other members will train the Secretariat on SOPs.
- There will be initial training and at least one training session per year on SOPs.
- The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

5. Assessment of IEC members

I. The IEC-VIMS member's performance should be evaluated once a year using an assessment form by the Chairperson.

II. The Chairperson should do self-assessment once a year

6. Maintenance of training records of the IEC-VIMS Members and the Administrative Staff

- The secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC-VIMS members.
- The copies will be filed in the individual member's files.
- The records regarding training copies of the secretariat will also be maintained in their respective files.

- **Assessment Form for Ethics Committee Members**

1. Current tenure
2. Terms served
3. Training received (Training record to be attached)

4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. Participation in SAE report review process- Yes/No
8. Participation in site monitoring visits -
9. Number and type of continuing training workshops organised for IEC-VIMS members (applicable to Member Secretary)
10. Number and type of continuing training workshops organised for staff of the IEC-VIMS secretariat (applicable to Member Secretary)
11. Any other significant contribution to the field of research ethics
12. Remarks by the Chairperson on the self-assessment

Training Records of the Member (Trainings in house + attended outside):

Name of the Member : **Designation in IEC-VIMS :**					
Date	**In House/Outside**	**Name/Names of Trainer/s**	**Topic**	**Organizer**	**Place**

- **Self-Assessment Form for IEC Chairperson**

1. Current tenure-
2. Terms served -
3. Training received -
4. Type of training received -

5. No. of meetings held in current year -
6. No of meetings attended-
7. Whether quorum requirement fulfilment ensured as per schedule Y in IEC-VIMS meetings
8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics

Any other comments _____

18. Role and responsibilities of ethics committee:

- The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
- The EC must ensure ethical conduct of research by the investigator team.
- 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.
- 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.
- The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- 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.
- Responsibilities of members should be clearly defined

- The SOPs should be given to EC members at the time of their appointment.
- 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
- The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
- 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.
- The EC should recommend appropriate compensation for research related injury, wherever required.

19. Term of reference of IEC –VIMS members

1. **Chairperson:**
    - 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 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.

2. Member secretary:

- 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 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.

- In case of anticipated absence of the Member Secretary, the Acting Member Secretary will be nominated by the Chairperson and / or the Member Secretary and documentation for the same will be maintained. The Acting Member Secretary will perform the duties of the Member Secretary and have all the powers of the Member Secretary for that meeting

3. Basic medical scientists

- 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.

4. Clinicians

- 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.

5. Legal experts

- 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

6. Social scientist/ Philosopher/ ethicist/theologian

- 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.

7. Layperson

- 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.

20. Procedure for proposal submission

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.

2. All relevant documents should be enclosed with application.

3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/Collaborators should be forwarded by the Head of the Department.

4. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.

6. The decision of IEC-VIMS will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

21. Documentation

a) All research proposals should be submitted with the following documents:

b) Title of the project

c) Names of the PI and Co-investigators with designation.

d) Name of any other Institute/Hospital/Field area where research will be conducted.

e) Approval of the Head of the Department.

f) Protocol of the proposed research.

g) Ethical issues in the study and plans to address these issues.

h) Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow–up cards, etc. to be used in the study.

i) Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).

j) For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.

k) Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.

l) Source of funding and Budget along with the supporting documents.

m) Indemnity issues including insurance for the compensation to the participants etc.

n) An undertaking to immediately report Serious Adverse Events (SAE) to IEC-VIMS.

o) Statement of conflicts of interest, if any.

p) Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.

q) Any other information relevant to the study.

r) Agreement to submit annual progress report and final report at the end of study.

s) The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

22. Review procedure

a) Meetings of IEC-VIMS shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.

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

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

d) PI should be available during the meeting and may be invited to offer clarifications.

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

f) The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

23. Element of Review

a) Scientific design and conduct of the study.

b) Approval of scientific review committee and regulatory agencies.

c) Assessment of predictable risks/harms and potential benefits.

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

e) Management of research related injuries, adverse events and compensation provisions.

f) Justification for placebo in control arm, if any.

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

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

i) Protection of privacy and confidentiality of subjects.

j) Involvement of the community, wherever necessary.

k) Protocol and proforma of the study including the consent form.

l) Plans for data analysis and reporting.

m) Adherence to all regulatory requirements and applicable guidelines.

n) Competence of investigators, research and supporting staff.

o) Facilities and infrastructure.

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

24. REVIEW OF RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATION

- **Purpose:**

This describes the requirements and process of review of research that involves vulnerable participants.

- **Scope**:

This covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IEC-VIMS

- **Responsibility**:
  - ✓ It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines.
  - ✓ IEC-VIMS Chairperson / Member Secretary are responsible for ensuring that IEC-VIMS members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes.
  - ✓ The Member Secretary/ Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for securing consulting expertise as and when required for selected reviews.
  - ✓ IEC-VIMS members are responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion.
- **Procedures:**
  - ✓ **Definition of Vulnerable Population:** Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. They are the individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

A. Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.);

B. 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. Children (up to 18 years)

D. Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);

E. Tribals and marginalized communities;

F. Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;

G. Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;

H. Terminally ill or are in search of new interventions having exhausted all therapies;

I. Suffering from stigmatizing or rare diseases; or

J. Have diminished autonomy due to dependency or being under a hierarchical system

(Students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

25. Reviewing protocols with vulnerable participants:

a) The protocol should be reviewed as described already under the “Review Procedures”.

b) In addition to that, the protocol should be reviewed to assess if the following points are addressed:

c) Can the research be performed in any other non-vulnerable participants?

d) Is there justification to use vulnerable population?

e) Do the benefits justify the risks

f) Are the participants selected equitably

g) Have the measures to protect Autonomy of the vulnerable population been described

h) Appropriate Review forms are used

i) **Reviewers:** In addition to all members of the IEC-VIMS, the Chairperson and Member Secretary include one or two experts who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. A representative of the vulnerable population also can be included.

j) **Decision:** The decision on allowing trials on vulnerable populations will be taken in a full board meeting of IEC-VIMS. The decision will be communicated to the PI. Wherever necessary the IEC-VIMS approval should state that if in future the vulnerability status of the participant's changes, for e.g. unconscious patient gaining consciousness, the participant will be re-consented.

26. Checklist for Research Involving Children

(To be filled by PI and submitted to IEC ; To be cross verified by Reviewer During Review) –Applicable for Regulatory Trials Only.

Name of Principal Investigator :

Title of the Protocol :

To be done by Principal Investigator	**To be done by Reviewer**		
Risk –Benefit Assessment : (Tick the appropriate answer)	**Risk –Benefit Assessment : (Tick the appropriate answer)**		
Less Than Minimal Risk ; Direct Benefit	Less Than Minimal Risk; Direct Benefit		
Less Than Minimal Risk; Indirect Benefit	Less Than Minimal Risk; Indirect Benefit		
Greater Than Minimal Risk; Potential benefit to child	Greater Than Minimal Risk ; Potential benefit to child		
Greater Than Minimal Risk; No direct benefit, offer knowledge about child's condition/disorder	Greater Than Minimal Risk ; No direct benefit, offer knowledge about child's condition/disorder		
	Yes	**No**	**NA**
1. Does the research pose greater than minimal risk to children?			
2. If yes: Are convincing scientific and ethical justifications given?			
3. If yes: Are adequate safeguards in place to minimize these risks?			
4. Does the study involve healthy children?			

a) If yes: Is the inclusion of healthy children justified?			
5. Are the studies conducted on animals and adults appropriate and justified?			
a) If No: Is the lack of studies conducted on animals and adults justified?			
6. Will older children be enrolled before younger ones?			
7. Is permission of both parents necessary?			
a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
b) If Yes: Are the conditions acceptable?			
8. Will efforts be made to ensure that parent's permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
9. Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
10. Are provisions made to protect participants" privacy and the confidentiality of information regarding procedures?			
11. Are provisions made to protect participant's privacy and the confidentiality of information regarding procedures?			

12. Are there special problems that call for the presence of a monitor or IEC-VIMS member during consent procedures?			
13. Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?			
14. Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
15. Does the research involve possibility of findings which may have implications for other family members? (for eg. genetic risk, HIV infection, Hepatitis C)			
16. If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
17. Are parents required to be present during the conduct of the research? (Are proposed participants‟ very young?)			

Signature of the Principal Investigator with Date

To be filled by Reviewer:

Comments of the Reviewer :	**Recommendations of the Reviewer :**
Name and Signature of the Reviewer with Date :	

27. DECISIONS MAKING

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

2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.

3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

4. Revised proposals may be subjected to an expedited review.

5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC-VIMS.

    A. PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC-VIMS.

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

    C. The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC-VIMS.

28. Communicating the Decision

A. Decision will be communicated to PI by the Member Secretary in writing.

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

C. Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials - After the approval from IEC-VIMS, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Dean with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost. The drug trial shall be started by the PI after the agreement is signed by both the parties and required regulatory approvals are available for the concerned trial.

29. Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated immediately to IEC-VIMS. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC-VIMS along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC-VIMS.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC-VIMS.

30. Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC-VIMS.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

31. Updating IEC-VIMS Members

1. All relevant information on ethics will be brought to the attention of the members of IEC-VIMS by the Member Secretary.
2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

32. HANDLING CONFLICT OF INTEREST AMONG ETHICS COMMITTEE MEMBERS

Purpose:

This is to describe the process to identify and manage conflict of interest among IEC-VIMS members.

Scope:

This covers the policy related to identification, declaration and management of conflict of interest and is applicable to all IEC-VIMS members.

Responsibility:

All IEC-VIMS members are responsible for self-identifying and disclosing the conflict of interest. The Chairperson of IEC-VIMS is finally responsible for ensuring that all members of IEC-VIMS self-declare conflict of interest during review of research proposals.

Procedure:

- **Information to members on conflict of interest:**

  ✓ During the appointment of members, one of the conditions is "To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any at appropriate time".

  ✓ The member will be signing the consent letter after going through the terms and conditions in the appointment letter.

  ✓ The conflict-of-interest policy of the IEC-VIMS will be explained to the members on induction. It will be a part of the trainings imparted to the members

- **Types of Conflict of Interest (COI):**

a) **Personal COI**: If the investigator of a research proposal has close and immediate family relationship with the member of IEC-VIMS (spouse, son/daughter, parents, sibling, dependent); If the IEC-VIMS member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come

for review in IEC-VIMS; If a research proposal is submitted by a departmental colleague with whom the member has conflict of interest (dispute, bias, any benefits, etc.. ,) if applicable and if the member feels there is a conflict of interest.

b) **Professional COI**: If the IEC-VIMS member or his/her immediate family member serves as trustee, Dean, manager, or scientific advisor of the funding agency sponsoring the research.

c) **Financial COI**: If the IEC-VIMS member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

- **Procedure for Declaring COI:**

✓ The IEC-VIMS member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared in the format provided in SOP of IEC-VIMS, and submitted to the member secretary.

✓ The IEC-VIMSmembers should not participate in discussing, or decision making on research proposal applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC-VIMS.

✓ If IEC-VIMS member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC-VIMS Secretariat and return the documents.

- ✓ If IEC-VIMS member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC-VIMS secretariat so that the review is reassigned to other members.

- ✓ If IEC-VIMS member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC-VIMS meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed

- ✓ The IEC-VIMS member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

- ✓ If an IEC-VIMS member finds that he/she has a COI during the conduct of a research project approved by IEC-VIMS, he/she shall report the conflict to the IEC-VIMS at the next IEC-VIMS meeting.

- ✓ At the beginning of each meeting, the IEC-VIMS Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC-VIMS member having conflict discloses the existence of the conflict just before the review of the relevant item begins.

- ✓ If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chairperson should be appointed for discussion on such a project.

- ✓ When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the IEC-VIMS member

with the help of the IEC-VIMS Chairperson / Member Secretary or by IEC-VIMS Chairperson / Member Secretary (as applicable)

- ✓ The IEC-VIMS Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection. The IEC-VIMS shall not approve a research study proposal where a COI is not managed or eliminated.
- ✓ The declaration and management of COI should be recorded in the proceedings of the IEC-VIMS meetings.

33. Preparation of Agenda, Conduct of Meeting and Minutes of Meetings

Purpose:

The purpose is to describe the preparation of agenda, distribution of agenda, preparation for meeting, conducting the meeting and preparing minutes of meetings of IEC-VIMS.

Scope:

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all IEC-VIMS meetings.

Responsibility:

The Member secretary is responsible for preparation of the agenda, recording the minutes of meeting and circulation of the minutes to all members of IEC-VIMS. The Chairman conducts the meetings of IEC-VIMS, and approves the minutes of meeting.

Procedure:

The meeting schedule: The IEC-VIMS meeting is held once in three months. Frequency of the meetings is increased depending on the number of research proposals for full review.

Preparation of Agenda:

1. The research proposals received by the IEC-VIMS are categorized for review as: exempted from review, expedited review and full review. This is done by the Member Secretary who will do the initial scrutiny of the research proposals. The review is done only for the proposals categorized for expedited and full review. The expedited review will be done by the Chairperson, the Member Secretary and one member of IEC-VIMS. The full review will be done by all members of IEC-VIMS.
2. The research proposals categorized for full review will be included in the agenda for presentation during the meeting of IEC-VIMS. The expedited reviews and exempted from review are included for approval by all members in the meeting.
3. The format of the agenda is enclosed in this procedure. The agenda includes: quorum of previous meeting (list of members present and absent), approval of the minutes of previous meeting, presentation of the research proposals (full review) by the principal investigator, approval of the expedited reviews, presentation of the proposals categorized under “exempted from review” by the Member Secretary, and any other issues as recommended by the members and approved by the Chairperson. Other issues could be report of onsite monitoring, training needs, accreditation of ethics committee, serious adverse events, review of protocol deviations/amendments, continuing review of research studies, completion reports of research studies, revision of SOPs, changes in the committee composition, reports of the research studies, revision of SOPs, changes in the committee composition, report of subcommittees appointed by the Chairperson (if any) and emergency concerns.
4. The format of the agenda is enclosed in this SOP. The agenda includes: quorum of previous meeting (list of members present and absent), approval of the minutes of previous meeting, presentation of the research proposals (full review) by the principal

investigators, approval of the expedited reviews, presentation of the proposals categorized under "exempted from review" by the Member Secretary, and any other issues as recommended by the members and approved by the Chairperson. Other issues could be report of onsite monitoring, training needs, accreditation of ethics committee, serious adverse events, review of protocol deviations/amendments, continuing review of research studies, completion reports of research studies, revision of SOPs, changes in the committee composition, report of subcommittees appointed by the Chairperson (if any)and emergency concerns.

5. Only those research proposals and documents (informed consent documents, protocol deviation/amendment notifications, revised submissions, progress reports, and study completion reports) received ten days before the scheduled meeting will be included in the agenda.
6. The venue of meeting is ensured before sending the agenda to all members. The agenda will mention the date, time and venue of the meeting.
7. A hard copy of the agenda, copies for research proposals for review and review forms are sent to the members at least one week before the meeting. The secretariat is responsible for sending these documents to all members without fail. The institution provides the transport facility for the same.
8. Even if there are no research proposals for review, the committee shall hold meeting at least once in three month and discuss issues other than review of proposals.
9. If any member is unable to attend the meeting, he/she should inform the Chairperson (through the Member Secretary) well in advance. (Preferably one week before the scheduled date of meeting). If the Chairperson is unable to attend the meeting, he/she will inform the Member Secretary, and ask him to conduct the meeting with the Vice Chairperson as the acting Chairperson for the meeting.
10. All regular members of IEC-VIMS, independent consultants and principal investigators of research proposals categorized for full review are required to attend the meeting. If

any member is unable to attend the meeting they need to inform the Chairperson or Member Secretary by any means of communication. Independent consultants chosen for full review are intimated to attend the meeting during the presentation of those research proposals which they have reviewed.

11. The principal investigator should attend the meeting and present the proposal. Co investigators are allowed to attend the meeting.

Conduct of meeting:

1. The secretariat will help the Member Secretary in arrangements for the meeting.
2. The IEC-VIMS full board meeting will be held as per the schedule provided there is quorum as per requirement.
3. There should be the presence of minimum quorum members.
4. The signature of all members who attended the meeting will be taken on the attendance sheet.
5. Guests or observers may be allowed in the meeting, provided they have taken prior permission, and signed confidentiality agreement.
6. The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict. The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict prior to the start of the meeting.
7. If a Conflict Of Interest has been declared by a member, the Chairperson will ask the member concerned to leave the meeting room, when the concerned issue is being discussed.
8. The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
9. The Member Secretary will present the agenda of the day's meeting for discussion.

10. The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.
11. The Principal Investigators are asked to present the research proposals as per the order of proposals mentioned in the agenda. When one investigator is presenting the proposal, investigators of other research proposals should not be present in the meeting room. However, co investigators of the same research proposal (or guides in case of dissertations) are allowed to be in the meeting room. In case of informed absence of principal investigator, co-investigator may be allowed to make the presentation. However, if the members feel that co-investigator is not familiar with the protocol details, the principal investigator may be asked to attend the next meeting of IEC for the presentation.
12. The members of IEC-VIMS should not discuss on the decisions about the research proposals when the investigators are inside the meeting room. The members should discuss only after the investigator leaves the meeting room.
13. For other matters in the agenda (other than full review), the member secretary will present the review findings (expedited review), list of proposals under exempted from review, protocol deviations/amendments, etc.
14. Reports of any subcommittees will be presented in the meeting by the heads of respective committees, as per the agenda.
15. The proceedings of the meeting will be recorded by the Member Secretary. If the Member Secretary has Conflict Of Interest in any research proposal, the joint secretary will do this job.

Decision making:

The final decision on approval of a research proposal is by consensus. In the review forms, the members need to tick one of the following:

1. Approved

2. Approved with suggestions
3. Resubmit with revisions
4. Rejected

In the "Suggestions" of section of the form, member can write down his/her suggestions of any and points to be considered for revision of the research proposal. Reasons for rejecting the proposal also should be mentioned in this section of review form. Final decision is taken by consensus. The Chairperson ensures participation of all members in the deliberations. The decisions are based on risk assessment, scientific validity, and adherence to ethical principles for the initial and periodic approvals.

The independent consultants called to the meeting will be present only for the presentation of the concerned research proposal. He/she will give the opinion during the meeting and will leave the meeting room. They don't have any voting rights.

Minutes of meeting:

The minutes of the meeting are prepared by the member secretary on summarizing the discussions held in the meeting and decision taken by consensus.

Following are the contents of the minutes of meeting:

1. Date, time and venue of the meeting
2. List of members who attended and who were absent for the meeting
3. List of guests /observers who attended the meeting
4. Name of the individual who served as chairman for the meeting
5. Ensuring of quorum by the chairman
6. Ratification of minutes of the previous meeting : to be mentioned
7. Research proposals for full review : summary of discussions and approval status
8. Research proposals for expedited review : summary of discussions and approval status

9. Research proposals exempted from review : list of the proposals
10. Discussion of protocol deviations/amendments , with actions taken
11. Discussion of onsite monitoring visits if any, with actions taken
12. Discussion of progress reports and final reports if any , with actions taken

The minutes are prepared within 3 working days of the meeting day.

The minutes are sent to all members of the committee by e mail and their inputs are taken.

The Chairperson gives the final approval for the minutes.

The minutes are presented in the next meeting for ratification.

Communication of the Decision to Investigators:

1. The decision of the IEC is communicated to the Principal Investigators. All communications are done by the Member Secretary.
2. The communication of the decision will include:
   A. Name and address of IEC
   B. The date and place of the decision
   C. The name and designation of the investigators
   D. Protocol no. given by the IEC
   E. Title of the research proposal reviewed
   F. Version No., date, amendment no. of the protocol (for clinical trials)
   G. List of documents reviewed (for clinical trials)-clear description of these documents along with version No., and date.
   H. List of IEC members who attended the meeting-clear description of their role and affiliation
   I. A clear statement of the decision reached

J. Any advice by the IEC to the applicant including the schedule /plan of ongoing review by the IEC-VIMS

K. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed

L. In case of rejection, reasons for rejection will be clearly stated

M. Signature of the member secretary with date.

Calling an Emergency Meeting of IEC-VIMS:

The Member Secretary in consultation with the Chairperson may call for an emergency meeting on following occasions:

1. Urgent issues that, if not discussed and decided may have adverse impact on patient safety
2. Serious adverse events
3. Other issues deemed appropriate by the Chairperson or the Member Secretary

The Secretariat will endeavour to contact each and every IEC member and inform him/her about the date, time and venue of the meeting as well as the reason for calling for the meeting.

Calling additional meetings of IEC-VIMS:

The Member Secretary in consultation with the Chairperson can call for additional meetings depending on the requirement. These are the meetings other than emergency meetings. Additional meetings are called if the number of research proposals for full review are more than 15, and if the IEC-VIMSis not able to include discussion of issues such as progress reports, onsite monitoring, study completion reports, etc. in the monthly meeting due to constraint of time. The procedure for agenda, conduct and minutes is the same as that followed for the usual monthly meetings.

Agenda format

Meeting No. :

Date and Time of Meeting:

Venue of Meeting:

I. Ratification of the minutes of previous meeting

II. List of Research proposals for full review:

III. List of proposals for expedited reviews

IV. List of proposals exempted from review

V. Protocol deviations/amendments

VI. Study completion /progress reports

VII. Reports of onsite monitoring

VIII. Reports of subcommittees

IX. Any other issues

Format for Minutes of meeting:

Meeting No:

Date and Time:

Venue:

I. Members present and absent : list with designations

II. Guests or observers present : list with designations

III. Name of the individual who served as Chairperson

IV. Ensuring of quorum by the Chairperson

V. Ratification of the minutes of the previous meeting

VI. Research proposals for full review :

The Proceedings are recorded as follows:

Protocol No.	Title of the Study	Name of the Principal Investigator	Remarks by the members (Opinion/ Suggestion/ Other remarks)	Approval status

VII. Research Proposals for expedited review:

Protocol no.	Title of the study	Name of the principal investigator	Name of the members who did the expedited review, with remarks	Approval status

VIII. Research Proposals exempted from review:

Protocol no.	Title of the study	Name of the principal investigator	New/ Revised Submission	Approval status

IX. Discussion OF Protocol Deviations/ Amendments and actions taken:

Protocol no.	Title of the study	Name of the principal investigator	Protocol Deviation/ Amendment	Action taken

X. Discussion of reports of onsite monitoring

Protocol no.	Title of the study	Name of the principal investigator	Name of the members who did the expedited review, with remarks	Action taken with remarks of monitoring team

				members and final decision

XI. Discussion of reports of subcommittees

Team members	Purpose of the Subcommittee	Brief description of the work done by the subcommittee	Remarks of the Chairman

XII. Discussion of Progress Reports and Study Completion Reports

Protocol no.	Title of the study	Name of the principal investigator	Remarks on the report submitted	Action taken as per the requirement

34. Maintenance of Active Project Files, Archival / Disposal of closed files and Retrieval of documents

1. Purpose

To provide guidelines for preparation and maintenance of study files and other related documents for all IEC-VIMS approved ongoing projects as well as storage/archival/disposal of study files and other study related documents for projects which are completed and closed

2. Scope

This SOP applies to all active/closed protocol/study files and their related documents that are maintained in the IEC-VIMS office and archival site.

3. Responsibility

It is the responsibility of IEC-VIMS staff to ensure that all study files are prepared, maintained, and kept securely for the complete period of the study and for five years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time).

4. Active study files maintenance & archival of closed files

A Study Master File is the file comprising of all essential documents and correspondence related to the study/protocol. Study master file should be established at the time of initial submission in the IEC-VIMS office.

- The study files are assigned unique identifiers (serial project no.)
- All documents related to the study file are gathered, classified and combined together appropriately.
- All active files are kept in a secured file cabinet with controlled access. Only authorized individuals' i.e. IEC-VIMS Secretariat will have access to the files. The study files are maintained in an easily accessible and secure place for complete period of the study and at least 5 years after the study closure.
- All closed study files are separately archived.
- IEC-VIMS staff will archive the closed project files once the completion/status reports are reviewed by the IEC-VIMS. The completed/closed project files are clearly labelled and stored in the archival room. Only the IEC-VIMS Secretariat, auditors and the regulatory authorities would have access to these files.
- The records are stored by ITS on servers and are backed-up at regular intervals.
- Documentation of back-up for the IEC-VIMS database and electronic files is kept by IT programmer.

5. Disposal of closed files and copies of protocols and documents submitted for IEC-VIMS review.

The trial master file will be maintained in the IEC-VIMS office for complete period of the study and for five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed of in the central shredding facility. However, all the copies of the research projects and documents submitted for IEC-VIMS review will be shredded by the authorized IEC-VIMS personnel after the IEC-VIMS meeting without any notification to the Principal Investigator. A log book of disposed documents will be maintained.

6. Accessibility / Retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.

In case any investigator needs a copy of any document from the master file, he/she should make a written request (AX1–V5/SOP10/V5). The IEC-VIMS staff will furnish a copy of the required document within a week with the IEC-VIMS Secretary's consent. The IEC-VIM Swill issue a copy of the requested documents on formal written request.

For administrative purposes, the IEC-VIMS Secretariat can retrieve archived file(s) without requiring the Chairperson's approval. For this purpose the IEC-VIMS Secretary can authorize a staff member of the IEC-VIMS secretariat to physically retrieve a file.

7. Final Disposal of Master files

The master files will be disposed off by the IEC-VIMS secretariat after the archival period of 5 years. A formal written off register (AX2- V5/SOP 10/V5) will be maintained, providing details of the documents being written off / disposed off.

FORMATS

FORMAT FOR MEMBER COMMITTEE

Name, address, Qualifications and designation of the members of Ethics committee

Sl No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, email ID, and Mailing address	Designation/ Role of member in Ethics committee	Affiliation of member with institute that has constituted the ethics committee
					Chairman	
					Member Secretary/ Convener	
					Basic Medical scientist	
					Clinician	
					Legal expert	
					Social Scientist	
					Lay Person	

Commitments:

1. The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well- being of the trial subjects.
2. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
3. The Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
4. We agree to maintain adequate and accurate records after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

(Signature of the Chairman)
Date:

(Signature of the Member Secretary)
Date:

CURRICULUM VITAE FORMAT

Name:	
Qualification:	
Sex:	
Date of Birth:	
Education Details:	
PhD Thesis:	
Dean Thesis:	
DNB Thesis	
If any other Research activity done as part of curriculum (Please mention the Degree and title here)	
Designation:	
Experience: Teaching:	
Office Address:	DVVPF's Foundation Medical College and Hospital, Opp. Govt. Milk Diary, Post – MIDC, Vadgaon Gupta, Ahilyanagar - 414111
Permanent Address:	
Publication Details:	

(Name)
(Title)
DVVPF's Foundation Medical College and Hospital,
Opp. Govt. Milk Diary, Post – MIDC,
Vadgaon Gupta,
Ahilyanagar - 414111

FORMAT OF APPOINTMENT LETTER: CHAIRPERSON

To Date: _____

Sub: Appointment as Chairperson of IEC-VIMS

Dear Sir/ Madam,

I am pleased to appoint you as the Chairperson of IEC-VIMS with effect from _____. You will have a tenure of two years from this date.

As head of the institution, I assure you that IEC-VIMS will be provided with all required with all required infrastructure and facilities for its effective functioning. The Ethics Committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution.

Please find enclosed terms and conditions of your appointment, roles and responsibilities.

I request your services in the effective and efficient functioning of IEC-VIMS.

Congratulations and all the best.

With Regards,

Dean,

DVVPF's Foundation Medical College and Hospital, Ahilyanagar

Format of Terms and Conditions of Appointment, and Roles and Responsibilities of Chairperson

1. As Chairperson of IEC-VIMS, you shall conduct the meetings of IEC-VIMS and ensure active participation of all members in the discussions and deliberations.
2. As Chairperson of IEC-VIMS, you are required to verify and approve the SOP of IEC-VIMS in coordination with the Member Secretary
3. You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IEC-VIMS.
4. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
5. Be willing to sign a confidentiality agreement, and to maintain confidentiality of the documents and deliberations of ethics committee meetings
6. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.
7. You shall seek conflict of interest from members and ensure quorum and fair decision making
8. You are the authorized and responsible for handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data
9. You are the authority and responsible for approving the minutes of meetings,
10. You are the authority and responsible to review serious adverse events and take appropriate action as per guidelines.
11. You are the authority of IEC-VIMS to discuss with members and recommend to the Dean, DVVPF'S MEDICAL COLLEGE AND HOSPITAL and the disqualification of members (if required) before the completion of their term.

12. You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to lead the IEC team for onsite monitoring visits
13. You shall not keep any literature or study related documents with you after the discussion and final review
14. Be willing to undergo training or update programmes on relevant guidelines and regulations, research ethics, and good clinical practice during your tenure in the IEC-VIMS.
15. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.
16. One month notice on either side will be necessary prior to resignation/termination of appointment.
17. You will be responsible for making any communications on behalf of the IEC-VIMS to CDSCO and any other regulatory bodies

The Details of the roles and responsibilities of Chairperson and members of IEC-VIMS are mentioned in the policies and standard operating procedures of IEC-VIMS.

Dean
DVVPF's Foundation Medical College and Hospital

FORMAT OF APPOINTMENT LETTER: MEMBER SECRETARY

Date: _____

To

Sub: Appointment as Member Secretary of IEC-VIMS

Dear Sir/ Madam,

I am pleased to appoint you as the Member Secretary of IEC-VIMS with effect from _____. You will have tenure of two years from this date.

As head of the institution, I assure you that IEC-VIMS will be provided with all required with all required infrastructure and facilities for its effective functioning. The Ethics Committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution.

Please find enclosed terms and conditions of your appointment, roles and responsibilities.

I request your services in the effective and efficient functioning of IEC-VIMS.

Congratulations and all the best.

With Regards,

Dean,

DVVPF's Foundation Medical College and Hospital, Ahilyanagar

Terms and Conditions of Appointment, and Roles and Responsibilities of Member Secretary of IEC-VIMS

1. As Member Secretary, you are required to organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review; scheduling the meetings, preparing the agenda and minutes of meetings
2. You are authorized and responsible to assess the need for exemption from review, expedited review or full review
3. You are authorized to issue ethical approval letters, after approval from the committee
4. You are required to do the needful for the revision of SOP of IEC-VIMS in coordination with the Chairperson.
5. You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IEC-VIMS
6. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
7. Be willing to sign a confidentiality agreement, and to maintain confidentiality of the documents and deliberations of ethics committee meetings
8. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.
9. To organize IEC documentation, communication and archival.
10. To arrange for training of IEC secretariat and members
11. To ensure adherence of IEC functioning as per SOPs
12. To prepare for and respond to audits and inspections
13. You will be responsible for making communications on behalf of IEC-VIMS, to investigators, members of IEC-VIMS, sponsors and Head of the Institution.

14. You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to participate in onsite monitoring visits
15. You shall not keep any literature or study related documents with you after the discussion and final review
16. Willing to undergo training or update programs on relevant guidelines and regulations, research ethics, and good clinical practice during your tenure in the IEC-VIMS.
17. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.
18. One month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of Member Secretary are mentioned in the policies and standard operating procedures of IEC-VIMS.

Dean

DVVPF's Foundation Medical College and Hospital

FORMAT APPOINTMENT LETTER: MEMBER

(Clinician/ Basic Medical Scientist/ Lay person/ Social Scientist/ Theologian/ Legal Expert)

To Date: _____

Sub: Appointment as a Member of IEC-VIMS

Category: Clinician/ Basic Medical Scientist/Lay Person/Social Scientist/Theologian/Legal Expert.

Dear Sir/ Madam,

I am pleased to appoint you as the Vice Chairperson of IEC-VIMS with effect from _____. You will have a tenure of two years from this date.

I request you to kindly extend your cooperation to the Chairperson and Member Secretary of IEC-VIMS, in effective and efficient functioning.

As head of the institution, I assure you that IEC-VIMS will be provided with all required with all required infrastructure and facilities for its effective functioning. The Ethics Committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution.

Please find enclosed terms and conditions of your appointment, roles and responsibilities.

I request your services in the effective and efficient functioning of IEC-VIMS.

Congratulations and all the best.

With Regards,

Dean,

DVVPF's Foundation Medical College and Hospital, Ahilyanagar

Terms and Conditions of Appointment, and Roles and Responsibilities of a Member of IEC-VIMS

1. As a member of IEC-VIMS you need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to participate in onsite monitoring visits and review of serious adverse events as and when required. You are required to attend regular as well as emergency meetings of IEC-VIMS. You are expected to participate actively in all discussions and deliberations of IEC-VIMS.
2. You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IEC-VIMS
3. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
4. Be willing to sign a confidentiality agreement, and to maintain confidentiality of the documents and deliberations of ethics committee meetings
5. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.
6. You shall not keep any literature or study related documents with you after the discussion and final review
7. Be willing to undergo training or update programs on relevant guidelines and regulations, research ethics, and good clinical practice during the tenure as ethics committee member
8. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.
9. One month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of a member are mentioned in the policies and standard operating procedures of IEC-VIMS.

Dean

DVVPF's Foundation Medical College and Hospital

Format Appointment Letter of Independent Consultant

To

Dr. _____

Dear Sir/Madam,

Sub: Proposal of Appointment as "Subject Expert" for Institutional Ethics Committee

I am pleased to appoint you as a member in "The Panel of Subject Experts" of DVVPF'S MEDICAL COLLEGE AND HOSPITAL Institutional Ethics Committee. Following are the terms and conditions of appointment.

1) You will not be a regular member of Ethics Committee

2) As a subject expert, you are required to review of research proposals pertaining to your subject/specialty area, whenever you are requested by the Member Secretary of Ethics Committee. Whenever requested, you are required to complete the review in the stipulated time of one week. Review form which is provided along with the proposal needs to be filled.

3) For the research proposals categorized under "Full Review", you have to attend the meeting of Ethics Committee along with the filled review forms. You have to be present in the meeting only for the presentation of that proposal reviewed by you. You can clarify any queries with the researcher/investigator during the meeting, and will share your opinion with the regular members of ethics committee.

4) For the research proposals categorized under "expedited review", you will not be attending the meeting. Only the filled review form has to be sent to Member Secretary of Ethics Committee.

5) You will not have any voting rights in the Ethics Committee meeting

6) You need to sign a letter of conflict of interest, and declare to maintain confidentiality of the discussions and reviews

7) You will be paid a remuneration of Rupees _____ /proposal for the review work done

Dean

DVVPF's Foundation Medical College and Hospital

Format of Appointment of Member of "Subject Expert Panel"

To

The Dean
DVVPF'S Medical College and Hospital

Sub: Consent to be the member of Subject expert panel of IEC-VIMS

Ref: Appointment letter no. ----------; Dated ----------

Dear Sir,

In response the appointment letter, I give my consent to be the member of DVVPF'S Medical College and Hospital Institutional Ethics Committee "**Subject Expert Panel**". As a subject expert, I shall do review of research proposals pertaining to my subject/specialty area, whenever I am requested by the Member Secretary of Ethics Committee. I shall participate in the ethics committee meetings whenever asked to do so. I shall maintain the entire research project related information confidential. I am ready to declare conflict of interest whenever I have the conflict of interest with regard to any research proposal. The research proposal-related materials given to me for review will be returned to ethics committee once I complete the review process.

Thanking You,

Yours Sincerely,

Signature:
Name:
Designation and Department/Affiliations:
Date:
Place: IEC-VIMS

CONFIDENTIALITY AGREEMENT FORM FOR IEC-VIMS MEMBERS

In recognition of the fact, that I, _____ (Member's name, his/her position on IEC-VIMS and affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC-VIMS and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the IEC-VIMS is based on individual merits and not as representative of a home province, territory or community or as a delegate of any organization. The IEC-VIMS must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IEC-VIMS, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the IEC-VIMS. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC-VIM. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained.

I, _____ (name of the IEC-VIMSmember) have read and accept the aforementioned conditions as explained in this Agreement.

Signature:

Date:

Chairperson's Signature:

Date:

[The original (signed and dated Agreement) will be kept on file in the custody of IEC. A copy of the same will be given to the Undersigned.]

I acknowledge that I have received a copy of this agreement signed by the IEC-VIMS Chairperson and me.

Signature:

Date:

CONFLICT OF INTEREST/ DECLARATION FORM FOR IEC-VIMS MEMBERS

To

Chairperson,

DVVPF'S Medical College and Hospital Institutional Ethical Committee (IEC-VIMS)

Dear Sir,

I am aware of the COI policy of IEC-VIMS. I herewith declare my conflict of interest with regard to the following research proposal submitted to IEC-VIMSfor review.

Protocol No. :

Study Title:

Name of Principal Investigator:

Type of COI (Personal/ Professional/Financial) and the Reason:

Hence, I stay away from reviewing this research proposal, any deliberations/discussions on this study, and refrain from any decision making.

Name and Signature of Member
Date:

Name and Signature of Chairperson:
Date:

CONFLICT OF INTEREST AGREEMENT FORM FOR INDEPENDENT CONSULTANTS (IC)

- I understand that it is the policy of the IEC-VIMS that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC-VIMS.

- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IEC-VIMS to me.

- In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to IEC-VIM Sand refrain from reviewing it.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature of IC:

Date:

Chairperson's Signature:
Date:

I acknowledge that I have received a copy of this Agreement signed by the IEC-VIMSChairperson and me.

Signature:
Date:

[The original (signed and dated Agreement) will be kept on file in the custody of the IEC-VIMS. A copy will be given to you for your records]

RESEARCH PROPOSAL APPROVAL FORM
(With/ without fund)

SECTION A: APPLICANT DETAILS

A. 1	**Principle investigator** **Name** **ID number** **Program and Department** **Designation of principle investigator** **Contact email** **Contact No.**	
A.2	**Co-investigator/s (research team)**	

No.	Name	Participation type	Program/ Department	Designation	Contact details

SECTION B: DETAILS OF RESEARCH PROJECT

B.1	**Project overview**	
B.1.1	**Title**	
B.1.2	**Project Summary (maximum up to 250 words)**	
B.1.3	**Expected duration of project** **Expected start date** **Expected finish date**	
B.2	**Material and methods**	
B.2.1	**Aims of the research project**	
B.2.2	**Objectives of the research project**	
B.2.3	**Methodology**	

B.2.4	**References (Maximum up to 5)**	
B.3	**Investigators, collaborations and funding**	
B.3.1	Expected location (where will the study take place)	
B.3.2	Collaborations if any (other program, university/ institution external to VIMS etc.)	
B.3.3	Funding sources	

B.4	**Intra-mural fund (Fill in this section if you are seeking for research fund)**	
	Purpose	**Amount**
	Staff	
	Travel	
	Chemicals/Animals/Kits	
	Equipment	
	Miscellaneous if any	
	Total	

B. 5	**Requirement for ethical committee clearance**	
B.5.1	Institutional Human Ethics Committee	
B.5.2	Institutional Animal Ethics Committee	
B.5.3	Are other permissions and approvals required (if the proposed study is outside DVVPF's Foundation Medical College and Hospital, this may include other ethics committees, gatekeepers etc.)?	
B.5.4	If your answer to the above question was yes please specify.	

B.6	Facilities and equipment		
B.6.1	Facilities and equipment currently existing in the institution (provide details)		
B.6.2	Equipment planned to purchase (provide details)	**Name of the equipment**	**Purpose**
B.6.3	Equipment and facilities available in nearby institution or hospital, investigator intends to use		

SECTION C: Principal Investigators Bio-data

1	**Name**		
2	**Total experience (Teaching/Industrial/Research/Clinical)**		
3	**Date of birth**		
4	**Complete postal address (As per your passport/ID card)**		
5	**Present address for communication (Should include phone number and e-mail ID)**		
6	**Educational Qualification**	**Degree**	**Institution**
7	**Publications from last 5 years (Maximum up to 5, attach a print copy of the same with the application)**		

SECTION D
Declaration by Investigator/Investigators

1. I/We agree to the rules and regulations of the college/department/ethics committees.
2. I/we submit expenditure report once in a year and final expenditure report after completion of project/at the end of the duration/end of cancellation of project.
3. I/We submit bills and copies of invoice for every purchase made with the research grant.
4. I/we submit final research report with raw data to the research committee.
5. I/we submit research publications to the research committee.

S. No	Applicant	Name	Signature and date
1	Principal investigator		
2	Co-Investigator		
3	Co-Investigator		
4	Co-Investigator		
5	Co-Investigator		

For office use only

Date of application received:

Signature of recipient:

Instructions and guidance

All are mandatory fields to be filled, wherever not applicable please indicate as “NA”.
Incomplete form cannot be processed further.
*Note: Upon successful completion of technical review, the applicant will be directed to apply for permission from ethical committee.

Review form of IEC-VIMS (For Academic Studies – Biomedical and Health Research)

IEC-VIMS Protocol No.	
Title of the Protocol	
Principal Investigator	
Type of Submission	□ New □ Revised
Type of Review	□ Full □ Expedited
Date of Review	

1. Need for human participants is justified	□Yes □ No
2. Scientifically sound enough to expose subjects to risk	□Yes □ No
3. Relevant to contribute to further knowledge	□Yes □ No
4. Sufficient background information provided :	□Yes □ No
5. Objectives are clear and specific	□Yes □ No
6. Methodology is clear and detailed to achieve the objectives of the study	□Yes □ No
7. Inclusion and Exclusion criteria are clearly defined	□Yes □ No
8. Vulnerable participants are involved (Pregnant and lactating women, children, mentally challenged, seriously ill patients, foetus, economically or socially backward , healthy volunteers, captives, students, dependent staff)	□Yes □ No If Yes, are the vulnerable participants adequately protected? □Yes □ No
9. Is there physical/social/psychological risk/ discomfort?	□Yes □ No

10. What are the potential benefits from the study? (For the participant/For the Society/For improvement in Science)	Tick the appropriate : Benefit For the Participant : ☐Direct ☐Indirect Benefit for the Society : Direct ☐Indirect Improvement in Science: Direct ☐Indirect
11. Adequate measures taken to maintain Privacy and Confidentiality of study participants, samples and data	□Yes □ No
12. Is the investigator seeking waiver of consent?	□Yes □ No If yes, is the waiver of consent form filled appropriately and submitted? □Yes □ No
13. Is Participant Information Sheet and Informed Consent form (English) submitted as per the format of IEC-VIMS?	□Yes □ No
14. Is the Is Participant Information Sheet and Informed Consent form in Malayalam (Local Language) submitted?	□Yes □ No
15. Is Child assent form applicable for this study	□Yes □ No If Yes, is the appropriate assent form submitted? □Yes □ No
16. Budget proposal is submitted	□Yes □ No If Yes, is the Budget appropriate? □Yes □ No

17. Is there a conflict of interest for the Investigator?	□Yes □ No If Yes, is the conflict of interest acceptable? □Yes □ No

DECISION:	□ Approved □ Approved with Suggestions □ Resubmit with Revisions □ Rejected
Other Remarks and Suggestions, if any:	
Signature of the Reviewer with Date: Name of the reviewer:	

DECISION LETTER

Institutional Ethics Committee- Vikhe patil Institute of Medical Sciences

Date: _____ Dear Dr./Ms/Mr. ----------(Principal Investigator-name and address) Your research proposal was reviewed discussed in the ethics committee meeting held on ----------and the decision is as follows: Protocol title: "---------- "
Protocol No:
Principal Investigator: Co Investigators :
Name & Address of Institution :
New review: Exempt review/ Expedited review/ Full review
Review of Revised Submission: Date of review: Date and type of previous review, if revised application:
Decision of the Ethics Committee: ☐ Approved ; the project can be continued ☐ Modifications Recommended ☐ The Study should be discontinued
Suggestions /Reasons/Remarks:
Recommended for a period of :

Your research work will be continuously reviewed by ethics committee during the study period.

You are instructed to submit progress report of the research project once in every six months.

You should comply with the regulations and guidelines on biomedical research on human participants, and follow good clinical practice.

Ethics committee has the right to withdraw the approval if found necessary due to protocol violations, non-compliance to regulations and guidelines.

For any modifications/changes in protocol, investigators and study site you need to submit the proposal to ethics committee and get the approval.

You should report any serious adverse events in your site or any other site of this clinical trial to the ethics committee.

You need to submit the final report and summary at the termination of the study.

Following members of the IEC-VIMS were present and involved in decision making.

Name	Affiliations	Role in the Committee

Name and Signature of Member Secretary

Checklist: Requirements for research involving pregnant women & foetuses

Name of Principal Investigator:

Study Title:

Sl no	Questions	Yes	No	NA
1.	Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women have been conducted and provide data for assessing potential risks to pregnant women and foetuses?			
2.	Is the risk to the foetus not greater than minimal, or any risk to the foetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the foetus?			
3.	Any risk that is the least possible for achieving the objectives of the research?			
4.	Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived?			
5.	Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child?			
6.	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7.	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
8.	Do individuals engaged in the research have a part in determining the viability of a foetus?			

☐ If the response to any of the above is **NO**, the research should not be approved by the IEC-VIMS.

When research involves neonate after delivery

	YES	NO	NA
Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			
Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
Do individuals engaged in the research have a part in determining the viability of a foetus?			
A. Fetuses of uncertain Viability			
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research?			
OR			
The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means. Will there be a risk to the fetus from the research?			
Is the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally			

effective informed consent of either parents legally authorized representative obtained?			
B. Nonviable fetuses			
Will vital functions of the neonate be artificially maintained?			
Is there any risk to the neonate resulting from the research?			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means			
The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)			

Note: If the answer to any of the above is “No”, the research should not be approved.

Signature of Principal Investigator: _____
Date _____

Checklist for Research Involving Students, Employees or Residents

(To be filled by PI and submitted to IEC; to be cross verified by Reviewer during Review)

This form is applicable to a studies including regulatory trials and academic studies

Name of Principal Investigator:

Title of the Protocol:

	Yes	No
Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?		
Have the risks to participants been minimized?		
Have participants been assured that participation is voluntary (no signs of coercion)?		
Have participants been assured that privacy and confidentiality will be protected?		

Note: If response to any of the above is "No", the Research should not be approved.

Signature of Principal Investigator with Date

To be filled by Reviewer

Comments of the Reviewer :	Recommendations of the Reviewer
Name and Signature of the Reviewer with Date	