Standard Operating Procedures

For

Institutional Ethics Committee

Bharati Vidyapeeth (Deemed to Be University)

College of Nursing, Sangli, Maharashtra

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Contents

I. Short Description of SOP.

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee (Human Studies) (IEC) of Bharati Vidyapeeth (Deemed to Be University) College of Nursing, Sangli".

II. Adoption of SOP.

Bharati Vidyapeeth (Deemed to Be University) College of Nursing, Sangli herein after referred to as "BVDUCON, Sangli" has adopted these written Standard Operating Procedures (SOP/SOPs) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at BVDUCON, Sangli.

III. Objectives of SOP.

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of BVDUCON, Sangli is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants.

IV. Authority for constituting the IEC.

The Principal of BVDUCON, Sangli will appoint the Chairperson and all the committee members based on their competence, experience and integrity by request (Annexure-1). Members will confirm their acceptance to the Principal by providing all the required information for membership (Annexure-2). The Chairperson will furnish any information or report to the Principal, BVDUCON, Sangli when required.

V. Role and Responsibilities of IEC.

The IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and wellbeing of the human participants.

The IEC will ascertain whether all the cardinal principles of research ethics viz.,

Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations*.

IEC will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted in the institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency. In case IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the IEC shall forward it's report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority, to DCGI/ Chairman of the Expert committee constituted by the Licensing authority.

VI. Composition of IEC

IEC will be a multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The Chairperson/ Chairman of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and nonscientific persons and may also include members of public to reflect the different points of view.

There will be adequate representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The IEC of BVDUCON, Sangli will include

1. Chairperson/Chairman –From outside the institute
2. Member Secretary – From within the institute
3. Two persons- From basic medical science area
4. One clinician
5. One legal expert
6. One social scientist
7. One lay person (non-medical background) from the community

The main IEC is responsible to review research proposals (Synopsis) of Undergraduate, Post-Graduate and Ph.D students as per ICMR guidelines 2017.

VII. Requirements for IEC Membership

1. They are to be independent of political, Institutional, professional and market influences.
2. Members are drawn from different institutes and specialties to give multisectorial multidimensional structure.
3. Members should have qualities which include interest and motivation, commitment and availability, experience and education ,respect for divergent opinion ,interest in divergent work, integrity, diplomacy, trained in bioethics or conversant with ethical guidelines and laws of country.
4. In the interest of the Institute's research program, the IEC members including the Chairperson, Member Secretary will be selected by the Director/ Officer-in-Charge taking into consideration their expertise, research interests and experience in ethics.
5. Committee members will be selected based on the basis that they are willing to publicize full name, profession and affiliation. Their Curriculum Vitae should be submitted to the EC office for records.
6. Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.
7. The duration of appointment will be initially for a period of 3 years
8. At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.

9. A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
10. A member can tender resignation from the committee with proper reasons to do so.
11. All members should maintain absolute confidentiality of all discussions during the meeting.
12. 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 Head of the institution.
13. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term.
14. Conflict of interest need to be avoided.
15. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.
16. Members will be required to sign a confidentiality agreement at the start of their term
17. The committee shall maintain all the information regarding the clinical trial for at least 3 years after the completion of the trial.
18. The committee should inform in writing to the licensing authority in case of any changes in the ethics committee.
19. Licensing authority has the right to issue show cause notice in the event of any complaints and wrongdoing.
20. The authority has the right to cancel the registration of the committee

VIII. Quorum requirements

Minimum of 5 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution (Non-affiliated), and one member will be a non- scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 5 members with following representations:

(a) Basic medical scientists
(b) Clinician
(c) Legal expert
(d) Social scientist
(e) Lay person from the community.

IX. Conduct of IEC meetings

The Chairman will conduct all meetings of the IEC. In the absence of the Chairman, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Chairperson.

X. Independent consultants

The IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IEC.

XI. Application procedures

1. All research proposals should be submitted on any working day, the details of which are given under "Documentation". The applicant may ask for copy of SOP from the IEC.
2. Application of the research proposal along with relevant documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson IECBVDUCON, Sangli through member secretary. Receipt of the application will be acknowledged by the IEC office.
3. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the principal investigator. Principal investigator shall attend the meeting; make a brief presentation of the proposal and to clarify the points raised by the members.
4. The decision of the committee on the proposal 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.
5. All research proposals/clinical trials funded/sponsored by companies/ Agencies/ Multinationals etc. will be charged an administrative fee/ processing fee of ***Rupees Twenty Five Thousand for fresh proposals and Rupees Twenty Five Thousand for annual follow-ups/renewal review proposals.***

The administrative fee/ processing fee will be waived off for all non-funded/ funded (funded by organizations like ICMR, UGC, UNICEF, WHO, USAID, Non Profitable

Organizations etc)/research proposals by students & staff of BVDUCON, Sangli.

XII. Documentation

All Research proposals -hard copies along with soft copy (covering letter, proposals, Checklist etc in MS Word Format and certificates/insurance etc in PDF format on CD/DVD) along with the information and documents as specified in Annexures-3 and 4 shall be forwarded through the Head of the Department to IEC. **See also XIII. Review Procedures**.

XIII. Review procedures

1. The meeting of the IEC will be held twice in an academic year at every six month interval, i.e. unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The research proposals (04-hard copies with one softcopy) forwarded through Head of the Department to IEC then the proposals will be forwarded to Institutional Research Review Committee (IRRC) of BVDUCON, Sangli for review of scientific design of the research proposals. After approval from IRRC, the research proposals (08 copies to be submitted by PI with Soft copy on CD/DVD to IEC) will take up for review in scheduled IEC meeting. All research proposals unapproved by the IRRC, shall be resubmitted by PI with necessary corrections/ amendment as specified by IRRC (fresh 08-copies with amendments with Soft copy on CD/DVD) to IEC within the stipulated date as mentioned in the communication by IEC. IEC's member-secretary or secretariat will screen the proposals for their completeness and abiding IRRC decisions. Proposals If found incomplete will be summarily rejected and need to apply again as fresh application for consideration.
3. The IEC's member-secretary or secretariat will screen the approved research proposals by IRRC of BVDUCON, Sangli and depending on the risk involved categorize them into three types, namely, *exemption from review, expedited review and full review* (as per ICMR's Ethical Guidelines for Biomedical Research on Human Participants-2017).
4. Researchers will be invited to offer clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.
5. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

6. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final. The decisions will be minuted and Chairperson's approval will be taken in writing.

XIV. Aspects considered during review of research proposal by IEC

1. Approval by appropriate Institutional Research Review Committee (IRRC) of BVDUCON, Sangli (review of scientific design of the research Proposals).
2. Procedure for selection of subjects including inclusion / exclusion criteria and other issues like advertisement details.
3. Protection of privacy and confidentiality.
4. Involvement of the community, wherever necessary
5. Sample size (with justification)
6. Patient information sheet, informed consent form in English and in local languages.
7. Plans for data analysis and reporting.
8. Examination of potential benefits
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Examination of predictable risks/harms
11. Management of research related injuries, adverse events.
12. Compensation provisions.
13. Justification for placebo in control arm, if any
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure of study sites.
16. Criteria for withdrawal of patients, suspension or premature termination of a study.
17. Adherence to all regulatory requirements and applicable guidelines.

XV. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. The expert consultants will only offer their opinions.

5. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.
6. *Modified proposals will be reviewed by an expedited review* through identified IEC members.
7. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified
8. Procedures for appeal by the researchers will be clearly defined.

XVI. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified ICMR format. All the approvals will be valid for one year or for the duration of the project whichever is less.
2. The communication letters shall be collected by the PI from IEC office.

XVII. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
3. For PhD Scholars periodic status report of study should be submitted at every six month interval for review, along with information and documents as specified in Annexure- 7.
4. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
5. No Protocol deviation will be allowed.
6. Any new information related to the study should be communicated.
7. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
8. Change of investigators must be informed to the office of IEC within seven days.
9. Monitoring: Oversight mechanism will be in place to monitor the approved studies.

Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project.

10. Applicant – i.e PI must inform the completion of study (within 15 days) and must submit the result summary to IEC (within 90 days).

XVIII. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol, Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Drugs and cosmetics act, Directorate General of Health Services guidelines, Government of India, ICMR ethical guidelines for biomedical research in human participants -2017, as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

(iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study.

(iv) Any report of serious adverse event /death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee, DCGI and chairman of the expert committee constituted by the licensing authority.

(v) In case of injury or death occurring to the clinical trial subject, the sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

(vi) The sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority.

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority, the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within the stipulated period of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and DCGI/Chairman of the Expert Committee constituted by the Licensing authority under with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within the stipulated period of their occurrence as per Schedule.

(ii) The investigator shall provide information to the clinical trial subject through informed consent process about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

All the documents related to research proposals will be archived for a minimum period of 3 years by the PI/Researcher, following the completion / termination of the study.

XIX. Record keeping and archiving at the office of IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the institute, following the completion / termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the research proposals,

CD/DVD containing all the research proposals and documents to IEC office staff. IEC secretariat will archive one copy in IEC office and other copies will be destroyed after one year.

6. Following documents will be filed and archived with proper label on the top of file for easy identification

a. Constitution and composition of IEC (Human Studies)-BVDUCON, Sangli.
b. Curriculum Vitae (CV) of all members of IEC with records of training in Human ethics if any.
c. Standard Operating Procedures of IEC.
d. Annual reports
e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
f. The published guidelines for submission established by the EC.
g. Copy of all study protocols with enclosed documents, progress reports.
h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
k. Record of all notification issued for premature termination of a study with a summary of the reasons;
l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XX. Updating members of IEC.

1. All relevant new guidelines should be brought to the attention of the members.

2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review.

Procedure for Training and Assessment of Members

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC members and the secretariat. The Chairperson is responsible for assessment of all IEC members and complete a self-assessment exercise at prescribed intervals.

Procedure

Topics for training

1) IEC members should have knowledge of the following:
   - Relevant research ethics and regulatory guidelines
   - Roles and Responsibilities of IEC 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 specialities
   - SOPs of the IEC

2) Secretariat should have knowledge and relevant skills for conducting the following activities:
   - Knowledge about IEC SOP‟s and also guidelines for submission
   - Good communication skills – oral and written
   - Maintenance of IEC records – both soft and hard copy

Induction Training of new IEC Members

1) Every time a new committee is constituted, the members must undergo initial training within one month on ethics in clinical research and good clinical research and SOPs. An individual selected as a new member of the IEC will be required to attend one meeting as an „Observer‟ before being inducted as a member of the IEC. 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.
2) The newly inducted member will be encouraged to undergo training on good clinical practice, bioethics and guidelines on clinical research. The authorities may sponsor the member for such trainings.
3) The new member will receive trainings from any member of IEC or Chairperson or Member Secretary on the above topics. An expert from clinical research, bioethics or GCP will be invited to IEC to give training
4) The in house training sessions of IEC will have pre test and post test to assess the effectiveness of trainings.
5) The Member Secretary and the Chairperson will orient all the members on the SOP of the IEC.

Ongoing (On Job and Developmental) Trainings at IEC:

- 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 IEC may sponsor the members for such trainings.
- The Member Secretary of IEC 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, or an external GCP trained personnel or a bioethics expert. The trainings is imparted not only to the IEC members but, also to the institutional faculty who are investigators of ongoing research studies or potential investigators.

Training of the Secretariat: The IEC 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.

Assessment of IEC members

1. The IEC members‟ performance should be evaluated once a year using an assessment form by the Chairperson.
2. The Chairperson should do self-assessment once a year

Maintenance of training records of the IEC 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 members. The copies will be filed in the individual members‟ files. The records regarding training copies of the secretariat will also be maintained in their respective files.

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

Name of the Member : **Designation in BVCONIEC :**					
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 fulfillment ensured as per schedule
8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics
10. Any other comments _____

XXI. Terms of Reference

Terms of reference will be maintained in the office of IEC. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts / scientific review members *etc.*

The Constitution of IEC

Selection, Roles and Responsibilities of Members of IEC

Purpose: To describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of members of IEC, and the procedure for maintaining confidentiality of all activities and documents.

Scope: To appoint the members of IEC; defining their roles and responsibilities

Responsibility: The appointment of the members of IEC will be done by the Head of the Institution. And all involved personnel should follow the guidelines.

Procedure:

- The appointing authority for the IEC is Head of the institution
- Head of the institution appoints the Chairperson, the Member Secretary and other members of the committee. The Principal office sends an official request letter to the members.

- Then the members will confirm their acceptance to the Principal office 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 Principal will issue the final appointment order.

Composition of IEC:

The IEC is multi-disciplinary and multi-sectorial in composition. It is independent and shall have 7 to 15 members. The Chairperson shall be from outside the institution. The member Secretary will belong to the institution. There will be adequate representation of age and gender, and mix of scientific and non-scientific members. The basic composition of IECBVDUCON, Sangli is as per the guidelines of ICMR 2017.

The Composition shall be as follows:

Chairperson (Non-affiliated to the institution)

The Chairperson and Member Secretary will not have the dual roles in the ethics committee. They can't fulfill the role of a member (clinician/basic medical scientist/social scientist/legal expert, etc.) as it interferes with their own responsibilities.

All members including Chairperson, Member Secretary will review the research proposals. The Member Secretary does not have voting rights. Chairperson will exercise voting if it is required to make a decision on ethical approval to a research proposal.

Criteria for Selection of IEC members:

I. Chairperson:

1. Should be from outside the institution
2. Should have a minimum of three years experience as a member of an IEC
3. Should have undergone training in "Good Clinical Practice" and "guidelines for conducting biomedical research on human beings"
4. Should not have any known record of professional misconduct

II. Member Secretary:

1. A senior faculty from the institution with a postgraduate degree, and with a minimum experience of five years in the institution.
2. Should have undergone training in "Good Clinical Practice" and "guidelines for conducting biomedical research on human beings"

3. Should have worked as a convener/member of any committees/core teams of the Institution
4. Should have good communication skills
5. Should not have any known record of professional misconduct

Members:

1) Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC.
2) They should not have any known record of professional misconduct.
3) The basic medical scientists and clinicians should have post graduate qualifications.
4) The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community.
5) The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field.
6) The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/She also may be a representative of a non-governmental organization.
7) Theologian is a person involved in preaching of various religious activities while an ethicist has a background in law or philosophy. One of them is included as a member in IEC.
8) A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of the appointment. The member gets the voting rights once he/she undergoes training.
9) Requirements from Members when they give consent to be the members of IEC:
    a. The secretariat should collect a copy of recent curriculum vitae from all the members.
    b. The copies of degree certificates and medical council registration certificates should be collected from medical members of committee.
    c. 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.

Consent Letter and Confidentiality agreement from Members:

1) When the members agree to be part of IEC, 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 IECBVDUCON
2) The staff of secretariat of IEC has to sign an agreement of maintaining confidentiality.
3) Chairperson of IECBVDUCON will sign on all the confidentiality forms of members and secretariat staff.

Policy to Handle Conflict of Interest among Ethics Committee Members

All IECBVDUCON members are responsible for self-identifying and disclosing the conflict of interest.

The Chairperson of IECBVCON is finally responsible for ensuring that all members of IECBVDUCON self-declare conflict of interest during review of research proposals

Procedure:

Information to members on conflict of interest:

1) 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".
2) The member will be signing the consent letter after going through the terms and conditions in the appointment letter.
3) The conflict of interest policy of the IECBVCON 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):

1. **Personal COI:** If the investigator of a research proposal has close and immediate family relationship with the member of IECBVCON (spouse, son/daughter, parents, sibling, dependent) ; If the IECBVCON member is a collaborator, Principal investigator, co investigator, financer, research staff, consultant for a research proposal which has come for review in IECBVCON; 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.
2. **Professional COI:** If the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
3. **Financial COI:** If the IEC 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 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 IECBVCON, and submitted to the member secretary.
- The IEC members should not participate in discussing, or decision making on research proposals" applications reviewed at any level (exempt: expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.
- If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC Secretariat and return the documents.
- If an IEC 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 secretariat so that the review is reassigned to other members.
- If an IEC 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 meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
- The IEC 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 member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.
- At the beginning of each meeting, the IECBVCON Chairperson asks the members to

disclose any COI concerning any of the items on the agenda. During the meeting, IEC 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 member with the help of the IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)
- The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection. The IEC 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 IECBVCON meetings.

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:

1) When a regular member completes his/her tenure.
2) If a regular member resigns before the completion of the term.
3) If a regular member ceases to be a member due to any reason such as death or disqualification

To fulfill the membership requirements as per SOP/guidelines/regulations. The new member will be identified by the Chairperson based on the membership requirements after discussion by the IEC. The name of new member to be appointed may be suggested by members of IEC. The Chairperson sends the proposal to head of the institution. The final decision on appointment is taken by head of the institution.

Continuation of Membership after the Tenure:

- The tenure of the members in the IEC is three years. After the completion of three years, the decision on continuation of a member will be taken by the Principal of the

institution. Opinion of Chairperson and Member Secretary may be taken into consideration in this process.

- A member can have maximum two continuous terms in IEC. He/she may become a member again in IEC after a gap of at least two years.
- The Principal 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 Principal 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.

Conditions to be fulfilled by a member after appointment:

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

Termination of Membership

This refers to termination from membership even before the member completes his/her tenure. Reasons for termination may be resignation given by the member from the IECBVDUCON by himself/herself, resignation of the member from the institution, death of the member or disqualification of the member.

Voluntary termination: It is due to resignation of the member. The resignation has to be submitted in writing to Chairperson, IEC. One month prior notice is necessary for the resignation. It will be effective from the date of acceptance by the Chairperson.

For affiliated members: If a member resigns from the institution, even if he/she does not submit resignation to IEC, the membership to IEC stands automatically cancelled. This termination is effective once the member is relieved from the institution.

Disqualification:

A member is disqualified from the membership under following circumstances:

A) Misconduct :

a) If the Chairperson or the Member Secretary receives a communication in writing from public/investigators/ another member of IEC regarding misconduct of the member

b) If the Chairperson observes/gets information on any type of professional /ethical misconduct (not maintaining confidentiality /not declaring of conflict of interest/any type of bias towards research studies/investigators reviewed by IEC)

c) **Action to be taken:** The Chairperson satisfies himself/herself that prima facie a case exists before initiating any action. If in the opinion of the Chairperson, the matter of significance and integrity of the IEC could be questioned, he/she will first keep the member under suspension till the final decision is taken. During the period of suspension, the member will not have any voting rights, privileges and will not perform any duties of a member of IEC.

d) The Chairperson will call for a meeting of IEC, following the usual rules of quorum. The suspended member will be given sufficient opportunity to defend himself/herself in the meeting. The decision will be taken with the consensus.

B) Disqualification due to continuous absence: a member will be disqualified if he/she does not attend more than three consecutive meetings of IEC. If the member has given a prior intimation to Chairperson/member Secretary about the absence, the member will be given an opportunity to continue with the membership. This member will be issued a warning from Chairperson. However, the membership will cease if this habit repeats once again.

In case of absence without intimation for more than three consecutive meetings of IEC, the member is liable for disqualification. The member will be issued a one month notice by the Chairperson seeking explanation for the absence. If the member gives satisfactory explanation for the continued absence and assures attendance for future meetings, the Chairperson may decide on continuation of the membership. In the absence of any reply from the member, the Chairperson will discuss the matter of disqualification of membership in the meeting of IEC. Final decision on disqualification is taken by the Chairperson.

In all the above cases of disqualification, the Chairperson communicates to the Principal of the institution in writing. The decision of disqualification is communicated to the member by the Principal.

Roles and Responsibilities of IEC Members

4. **Chairperson of IEC:**
   i) To conduct meetings and to be accountable for efficient functioning of the committee
   ii) To ensure active participation of all members in all discussions and deliberations
   iii) Seek conflict of interest from members and ensure quorum and fair decision making
   iv) Handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data
   v) To ratify the minutes of previous meetings
   vi) To review serious adverse events with causality assessment
   vii) He/She is the final authority of IEC to take any decision on disqualification of members and recommend to the head of the institution for termination of the member.
   viii) He/She is the approval authority for SOPs of IEC
   ix) He/She is responsible for making any communications on behalf of the IECBVDUCON to DCGI and any other regulatory bodies.

5. **Member Secretary of IEC:**
   i) To organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
   ii) To schedule IEC meetings, prepare the agenda and minutes
   iii) To organize IEC documentation, communication and archival
   iv) To arrange for training of IEC secretariat and members
   v) To ensure that SOPs are updated as and when required
   vi) To ensure adherence of IEC functioning as per SOPs
   vii) To prepare for and respond to audits and inspections
   viii) To Ensure completeness of documentation at the time of receipt of protocols , and timely inclusion in the agenda for IEC review
   ix) To assess the need for exemption from review, expedited review or full review

6. **Basic Medical Scientist:**
   Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology, statistics, continuing review process, review of serious adverse events, progress report and final report.

7. Clinician/s:

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

ii) Ongoing review of the protocol, review of serious adverse events, progress report and final report.

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

iv) Thorough review of protocol, investigator's brochure and other protocol related documents

8. Lay Person:

i) Ethical review of the proposal, informed consent documents along with translations

ii) Evaluate benefits and risks from the participant's perspective, and opine whether benefits justify the risks

iii) Serve as a patient /participant/community representative and bring in ethical and societal concerns

9. Legal Expert:

i) Ethical review of the proposals, informed consent documents along with translations, MOU, clinical trial agreement, regulatory approval, insurance document, compensation proposals, other site approvals, investigator's undertaking, and protocol-specific other permissions.

ii) Interpret and inform members about new regulations if any.

10. Social Scientist:

i) Ethical review of the proposals, informed consent documents along with translations

ii) Assess impact on community involvement, socio-cultural context

iii) Serve as representative of community/society and bring in ethical and societal concerns

11. Secretariat of IEC:

Secretariat is composed of the clerical staff and attender.

i) Secretariat will assist the Member Secretary and joint Secretary in all their functions.

ii) The clerical staff is involved in receiving the proposals, preparing the communication letters, approval letters, and any other typing work assigned by Member Secretary and Chairperson.

iii) They are also involved in typing agenda for the meeting, typing the proceedings of meetings, and preparation for the meetings.

iv) The secretariat staff needs to sign a confidentiality agreement.

v) Attenders are involved in distribution of research proposals to members for review and physical arrangements for the meetings.

12. Responsibility of IEC Members (In General for all Members):

i) All members are expected to review the research proposals and attend the ethics committee meetings, and participate in the discussions and deliberations

ii) To review the revised submissions, additional submissions, progress reports and final reports

iii) To review the reports of serious adverse events, and recommend appropriate actions

iv) To carry out monitoring visits at study sites as and when needed

v) To maintain confidentiality of the documents and deliberations of ethics committee meetings

vi) To declare conflict of interest if any, to the Chairperson

vii) To participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

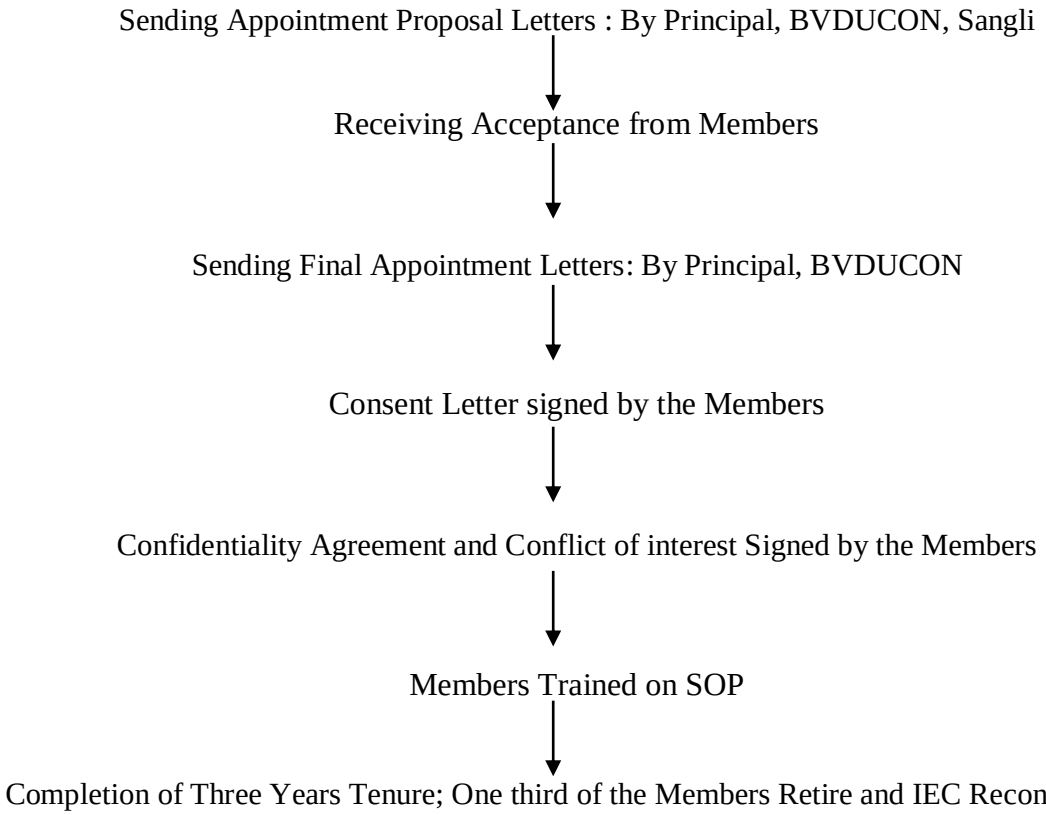
Payment of Remuneration to IECBVDUCON Members

i) The IECBVDUCON members are paid honorarium for attending meeting of IEC and onsite monitoring visit.

ii) The remuneration is decided by the head of the institution while appointing the members.

iii) In addition, the institution may sponsor the members to attend trainings on ethical guidelines and GCP.

Flow Chart: Constitution of IECBVDUCON



XXII. Administration and Management

- A full time secretariat and space for keeping records is available for a well-functioning of IEC.
- The members could be given a reasonable compensation for the time spared for reviewing the proposals.
- There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXIII. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a wholeirrespectiveofthespecialtyofresearch,therearecertainspecificconcernspertainingto specialized areas of research that require additional safe guards / protection andspecific considerations for the IEC to take note. The characteristics of such population are as follows:

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

The research involving populations or groups meeting the above characteristics of vulnerability constitutes:

- 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.);
- 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;
- Children (up to 18 years);
- Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- Tribals and marginalized communities;

- Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- Afflicted with mental illness and cognitively impaired individuals, differently abled –
- Mentally and physically disabled;
- Terminally ill or are in search of new interventions having exhausted all therapies;
- Suffering from stigmatizing or rare diseases; or
- Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defenceservices personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. To protect the vulnerable population the ICMR guidelines 2017will be followed as applicable.

The stakeholder's responsibilities in conducting the research among the vulnerable population or group include the following standard operating procedure:

Ethics Committees

- During IEC review meeting the members will determine and ensure
    - Whether the prospective participants for a particular research are vulnerable.
    - Whether inclusion/exclusion of the vulnerable population is justified.
    - The investigator do not increase harm or lessen benefits to the participants.
    - The benefits and risks to the participants and advicerisk minimization strategies wherever possible.
    - The IEC member will have frequent monitoring and review including the visit to the site.
    - The full committee will hold the review of such proposals and if necessary, the representative from the group of vulnerable population will be made to be present during the IEC review process.
    - The detailed justification on the exception to usual requirement to include the mentally ill or cognitively impaired.

Sponsors

- The sponsor (a government, an institution or a pharmaceutical company) must reasonably justify the inclusion of vulnerable groups in the proposal and make provisions for protecting their safety.
- The meticulous monitoring has to be in place to ensure the safety of vulnerable participants.

- In case the area of research is sensitive; The sponsor should ensures the protection of researcher/s and participants

Researcher/s

- Recognize the vulnerability of the participant and ensure additionalsafeguards are in place for their protection.
- Clearly justify inclusion/exclusion of vulnerable populations in the study.
- Conflict of interest must be addressed.
- Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio.
- Ensure that prospective participants are competent to give informed consent.
- Take consent of the Legally Authorised Representative (LAR) when a prospective participant lacks the capacity to consent.
- The assent must be obtained whenever possible for the population aged between
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.
- Research should be conducted within the purview of existing relevant guidelines/regulations.

ANNNEXURE- 1. PROPOSAL FOR IEC AS MEMEBR
A. Proposal Letter for Fresh Appointment

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)

COLLEGE OF NURSING, SANGLI.

Dr/Mr /Ms/ Mrs. _____

Address: _____

_____

Sub: Reconstitution of IEC BVCON.

Dear Sir /Madam,

The IECBVCON is glad to offer the proposal for appointment to our Institutional Ethics Committee. This offer is proposed on virtue of your academic and research background. Hence, I would love to acknowledge your service and contribution as a member for IEC. As a part of the constitution of IECBVCON, I request you to be the Member/Member Secretary /Chairperson of IECBVCON for the next three years, effective from _____.

A detailed appointment letter will be issued once we receive acceptance letter from you. I request you to submit your recently updated, signed CV along with certificates of training on GCP, Bioethics and guidelines on biomedical and health science research.

With Regards,

Principal BVCON, Sangli.

ANNNEXURE- 1. PROPOSAL FOR IEC AS MEMEBR
B. Appointment Proposal Letter for Reconstitution of IECBVCON

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI

Dr/Mr /Ms/ Mrs. _____

Address: _____

_____

Sub: Reconstitution of IEC BVCON.

Dear Sir /Madam,

The IECBVCON has completed tenure of three years. I acknowledge your services and contribution as a member of IEC for the last three years. As a part of the reconstitution of IECBVCON, I request you to be the Member/Member Secretary/Chairperson of IECBVCON for the next three years, effective from _____

A detailed appointment letter will be issued once I receive acceptance letter from you. I request you to submit your recently updated, signed CV along with certificates of training on GCP, Bioethics and guidelines on biomedical and health science research.

With Regards,

Principal BVCON, Sangli

ANNEXURE-2

ACCEPTANCE OF APPOINTMENT AS A MEMBER OF IECBVCON

To

The Principal
BVCON, SANGLI

Dear Sir,

Sub: Acceptance of Appointment as a Member of IECBVCON

Ref: Proposal Letter No. _____, Dated. _____

I am thankful to you for appointing me as a Member/Member Secretary/Chairperson of IECBVCON with effect from .

I herewith accept my appointment. I am ready to undergo regular training on good clinical practice, ethical guidelines on biomedical and health science research and bioethics as required. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain the entire research project related information confidential. I shall sign the confidentiality agreement, and shall declare conflict of interest if any as and when applicable.

I am submitting my recently updated, signed CV and certificates of training as requested by you.

Thanking You,

Yours Sincerely,

Signature:

Name:
Designation and Department/Affiliations:
Date:

ANNEXURE-3. APPOINTMENT LETTERS
Appointment Letter-A

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)

COLLEGE OF NURSING, SANGLI

INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

To :

Appointment Letter: Chairperson

Sub: Appointment as Chairperson of IEC BVCON

Dear Sir/Madam,

I am pleased to appoint you as the Chairperson of IECBVCON with effect from _____ You will have a tenure of three years from this date.

As head of the institution, I assure you that IECBVCON will be provided with all required infrastructure and facilities required 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.

You will be receiving an honorarium of Rs_____ per sitting for the services rendered by you.

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

I request your services in the effective and efficient functioning of IECBVCON, Sangli.

Congratulations and All the Best.

With Regards,

Principal,
Bharati Vidyapeeth (Deemed to Be University)
College of Nursing, Sangli.

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

1) As Chairperson of IECBVCON, you shall conduct the meetings of IECBVCON and ensure active participation of all members in the discussions and deliberations.
2) As Chairperson of IECBVCON, you are required to verify and approve the SOP of IECBVCON in co ordination with the Member Secretary.
3) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IECBVCON.
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 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 as and when applicable.
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 IECBVCON to discuss with members and recommend to the Principal BVCON 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 finalreview
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 IECBVCON.
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 IECBVCON to National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) and any other regulatory bodies.
18) The Details of the roles and responsibilities of Chairperson and members of IECBVCON are mentioned in the policies and standard operating procedures of IECBVCON as well.

ANNEXURE-3 APPOINTMENT LETTERS

Appointment Letter-B

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

To :

Sub: Appointment as Member Secretary of IECBVCON

Dear Sir/Madam,

I am pleased to appoint you as the Member Secretary of IECBVCON with effect from _____. You will have tenure of three years from this date.

As head of the institution, I assure you that IECBVCON will be provided with all required infrastructure and facilities required 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.

You will be receiving an honorarium of Rs_____ per sitting for the services rendered by you.

Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of IECBVCON.

Congratulations and all the best.

With Regards,

Principal
BVDUCON, Sangli

Terms and Conditions of Appointment, and Roles and Responsibilities of Member Secretary, IECBVCON

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 IECBVCON in co ordination with the Chairperson.
5) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IECBVCON.
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 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 as and when applicable..
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 IECBVCON, to investigators, members of IECBVCON, 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 finalreview
16) Willing to undergo training or update programmes on relevant guidelines and regulations, research ethics, and good clinical practice during your tenure in the IECBVCON.
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.
19) The details of the roles and responsibilities of Member Secretary of IECBVCON are mentioned in the policies and standard operating procedures of IECBVCON as well.

ANNEXURE-3. APPOINTMENT LETTERS
Appointment Letter-C

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

To:

Sub: Appointment as a Member of IECBVCON

Category: Clinician/ Basic Medical Scientist/Lay Person/Social Scientist/Theologian/Legal Expert Dear Sir/ Madam,

I am pleased to appoint you as a member of IECBVCON with effect from _____. You will have tenure of three years from this date.

You will be receiving an honorarium of Rs._____/per sitting for the services rendered by you. I request you to kindly extend your co operation to the Chairperson and Member Secretary of IECBVCON in effective and efficient functioning.

Please find the enclosed terms and conditions of your appointment, roles and responsibilities of Member and Chairperson. You will be issued a copy of the policies and standard operating procedures of IECBVCON once you sign the consent letter and confidentiality agreement. You will have the voting rights in the IEC only after you receive the initial training on policies and standard operating procedures.

Congratulations and all the best. With Regards,

Principal,
BVDUCON, Sangli.

Terms and Conditions of Appointment, and Roles and Responsibilities of

Member, IECBVCON

1) As a member of IECBVCON 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 IECBVCON. You are expected to participate actively in all discussions and deliberations of IECBVCON.

2) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the IECBVCON

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 as and when applicable.

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 programmes 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.

10) The details of the roles and responsibilities of a member of IECBVCON are mentioned in the policies and standard operating procedures of IECBVCON as well.

ANNEXURE-4. Consent Letter from Appointed Members

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

To
Principal
BVDUCON, Sangli.

Sub: Consent to be signed by the Chairperson/Vice Chairperson/Member Secretary/Member of IECBVCON.

Ref: Your letter No._____; Dated _____

Respected Sir/Madam,

In response to your letter, I give my consent to be the Chairperson/Vice Chairperson/Member Secretary/Member of BVCON Institutional Ethics Committee. I shall execute my roles and responsibilities as per the policies and standard operating procedures of IECBVCON, and as mentioned in my appointment order. I shall maintain high ethical standards, and will not be unduly influenced in discharging my assigned work.

I will sign the confidentiality agreement during my induction. I am aware of the conflict of interest policy of IECBVCON, and I will declare conflict of interest (if any) during my induction as a member, review of research proposals and decision making in IECBVCON.

Thanking You,

Yours Sincerely,

Signature:
Name:
Designation and Department/Affiliations:
Date:

ANNEXURE-5. A. Confidentiality Agreement to be Signed By Member of IECBVCON

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

Name of the Member:

Designation in IECBVCON:

I have been appointed as a member of the IECBVCON 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 is based on individual merits and not as an advocate or representative neither of a home province, territory or community nor as a delegate of any organization.

The IEC 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, 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 IECBVCON. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IECBVCON. 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 have read and accept the aforementioned conditions as explained in this Agreement.

Signature of the Member, with Date

Chairperson's Signature and Date

[The original (signed and dated Agreement) will be kept on file in the custody of the IEC.]

ANNEXURE-5. B. Confidentiality Agreement to be Signed By Secretariat Staff of IECBVCON

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

I, _____(Staff's name and Designation) herein referred to as the "undersigned", have been appointed as a staff of the IEC office. This agreement encompasses any information deemed confidential provided to the Undersigned in conjunction with the duties as a staff of the IEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him or her during his tenure of service.

I, _____(name of the IEC office staff) have read and I accept the 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 the IEC]

ANNEXURE-6. Conflict of Interest Declaration Form

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
COLLEGE OF NURSING, SANGLI
INSTITUTIONAL ETHICS COMMITTEE (IECBVCON)

To,
Chairperson,
IECBVCON,

Dear Sir,

I am aware of the COI policy of FMIEC.

I herewith declare my conflict of interest with regard to the following research proposal submitted to FMIEC for 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: