Bharati Vidyapeeth (Deemed to be University),

College of Nursing, Pune

Pune - Satara Road, Dhankawadi,

Pune 411043

Standard Operating Procedures (SOP)

Bharati Vidyapeeth (Deemed to be University),

College of Nursing, Pune-Ethics Committee

(BVDUCON, Pune-EC)

VERSION-I

Dated – January 2021

I. ShortTitle:

The following may be called as Standard Operating Procedures (SOP) Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune-Ethics Committee (BVDUCON, Pune-EC)

II. Adoption of SOP:

Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune

III. Objective

The Standard Operating Procedures (which shall be referred to as SOPs' henceforth in this document) aim to define the procedures that Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune – Ethics committee [BVDUCON, Pune-EC] shall follow in order to ensure quality, consistency and transparency in the ethics review and approval of research proposals and the monitoring of ongoing research at BVDUCON, Pune. These SOPs are based on the ICMR National ethics guidelines for Biomedical& Health research.

IV. Authority under which BVDUCON, Pune-EC is constituted

1. BVDUCON, Pune-ECis constitutedunder the head of the institute.

2. The Principal, Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune shall appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter.

3. Members shall confirm their acceptance to the Principal by providing all the required information for membership.

4. The Principal has the authority to accept resignation from Chairperson & all members if the need arises.

V. Role and responsibilities of BVDUCON, Pune-EC

1.The BVDUCON, Pune-ECshall review and monitor all types of research proposals conducted in BVDUCON involving human participants with a view to look after the rights, self-respect, safety and welfare/ well-being of all actual and potential research participants.

2.TheBVDUCON, Pune-ECshall take care that the 4 fundamental principles of research ethics viz autonomy, beneficence, non–maleficence and justice are explicitly considered during the planning, conduct, reporting, monitoring and review of proposed research.

3.TheBVDUCON, Pune-ECshall consider all aspects of the informed consent process (e.g. risk-benefit ratio, justice, privacy, confidentiality, distribution of burden / benefit and provision for appropriate compensation) with the utmost detail wherever required. Particular attention to this process will be paid where there is involvement of vulnerable groups (pregnant women, infants/children, disabled groups, prisoners, students of institutions, etc) as study participants.

4.All proposals shall be reviewed before the start of the study. After due clearance from the BVDUCON, Pune-ECthe study shall be monitored periodically (the timeframe for which shall be decided, and notified promptly, as demanded by individual protocols) throughout its implementation and until after the completion of the study. The minimum requirement is for annual periodic review—with a study report submitted at the end of one year of approval for the ethics committee to look at.

5.The approval after first submission will be for a period of 2 years for PG students & 5 years only for PhD scholars.The PI has to table his report to the BVDUCON, Pune-EC, 2 months before completion of the 2nd year to obtain continuation of the approval, if need arises. However, if he fails to do so he has to provide a written explanation to the BVDUCON, Pune-EC Chairperson who has the authority to then provide an extension of the approval until he gets the formal approval for the next year of operations. The BVDUCON, Pune-EC requires that periodic/ annual update reports and final report(s) be submitted during and after the completion of the project respectively.

6.Site visits for monitoring purposes might be initiated at the discretion of the Committee. The Committee shall also aim to ensure compliance with all regulatory requirements, applicable guidelines and laws.

7.The BVDUCON, Pune-ECshall be responsible for acting in the full interest of the research participants and concerned communities, while taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

VI. Composition of BVDUCON, Pune-EC

1.The BVDUCON, Pune-ECshall be multi-disciplinary and multi-sectoral in composition.

2.The Board shall consist of 7-15 members.

3.The Chairperson of the Board shall be from outside the Institution i. e. Bharati Vidyapeeth Deemed University, College of Nursing, Pune (BVDUCON, Pune)

4.Other Members shall be a blend of medical / non-medical, scientific and non-scientific persons including at least one lay person representing the community to reflect different viewpoints.

5.The Member Secretary shall be from BVDUCON, Pune and shall coordinate the secretariat of the committee in all its dealing.

6.A minimum of 5 persons shall be required to constitute a quorum without which the holdings and businesses of theBVDUCON, Pune-EC shall stand adjourned until such a number is available to conduct the same.

7.At least half of the committee Members will be from outside of BVDUCON, Pune (not employed) or non-affiliated.

Table- 1 Composition, Affiliation, Qualifications, member specific roles & responsibilities of BVDUCON, Pune-EC

Sr. No.	Members of EC	Description
1.	Chairperson Non-affiliated Qualification- A well respected person with prior experience of having served/ serving in an EC	The Chairperson shall conduct all meetings of the BVDUCON, Pune-EC& be accountable for independent & efficient functioning of the committee. Shall ensure active participation of all members in discussions. Shall ratify minutes of the previous meetings. In the absence of the Chairperson, an

		alternate Chairperson shall be elected by the Members present who shall conduct the meeting. The acting Chairperson should be a non-affiliated person & will have all the powers of the Chairperson for that meeting. Shall seek COI declaration from members & ensures quorum & fair decision making. Shall handle complaints against researchers, EC members, COI issues etc.
2.	Member secretary Affiliated Qualifications – Should be a staff member of the institution Should have knowledge and experience in clinical research and ethics	Shallorganize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review Shallschedule EC meetings, prepare the agenda and minutes Shallorganize EC documentation, communication and archiving Shallensure training of EC secretariat and EC members Shallensure SOPs are updated as and when required Shallensure adherence of EC functioning to the SOPs Shallprepare for and respond to audits and inspections Shallensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. Shallassess the need for expedited review/ exemption from review or full review. Shallassess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. Shallnsure quorum during the meeting and

		record discussions and decisions.
3.	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications – Medical person with qualifications in basic medical science like Pharmacology/Anatomy /Physiology	Shalldo the 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 shall review the drug safety and pharmaco-dynamics
4.	Clinician(s) Affiliated/ non-affiliated Qualifications – Should be individual/s with recognized medical qualification, expertise and training- MD General Medicine/Surgery	Shalldo the scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Shalldo the ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Shallreview medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. Shalldo thethorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	Legal expert/s Affiliated/ non-affiliated Qualifications – Should have a basic degree in Law from a recognized university, with experience Desirable: Training in medical law.	Shalldo theethical 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, HMSC for international collaboration, compliance with guidelines etc. Shall interpret and inform EC members about new regulations if any
6.	Social scientist/ philosopher/ethicist/ theologian Affiliated/ non affiliated Qualifications -	Shalldo theEthical review of the proposal, ICD along with the translations. Shall Assess impact on community involvement, socio–cultural context, religious

	Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	or philosophical context, if any Shall Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
7.	Lay person(s) Non-affiliated Qualifications – Literate person from the public or community Has not pursued a medical science/ health-related career in the last 5 years Is aware of the local language, cultural and moral values of the community Desirable: involved in social and community welfare activities	Shalldo theEthical review of the proposal, ICD along with translation(s). Shall Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. Shall Serve as a patient/ participant /community representative and bring in ethical and societal concerns. Shall assess on societal aspects if any.
8.	Scientific Member Affiliated/Non-affiliated Qualifications – Nursing expert from Medical surgical Nursing/ Community Health Nursing/ Child Health Nursing/ Mental Health Nursing/ Obstetric & Gynecological Nursing	Shalldo theScientific 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) Shallreview nursing care, facility and appropriateness of the principal investigator. Shalldo thethorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
9.	Scientific Member Affiliated/Non-affiliated Qualifications – Should have a basic	Shalldo theScientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study.

	degree in Bio-Statistics from a recognized university, with experience	Shall specifically assess for sample size, & plan for analysis.
10.	Member Affiliated Qualifications – Masters in Nursing	Shalldo theScientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Shalldo theongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Shall review nursing care, facility and appropriateness of the principal investigator.

VII. Roles and responsibilities of BVDUCON, Pune-EC Members

1. All Members of theBVDUCON, Pune-ECshall be required to undertake the review of research proposals, participate in meetings and businesses of the BVDUCON, Pune-ECand monitor any ongoing research.
2. EC shall review academic studies proposed by nursing students & PhD scholars. EC shall also review the studies proposed by nursing faculty members as a part of departmental or interdepartmental research activities.
3. EC shall reviewindependent researchers affiliated to Non-Government Organizations [NGOs], laboratories and organizations in the field of life science and who wish to conduct clinical research in Nursing.
4. For the external agencies a prescribed fee of Rs. 5,000/- (five thousand) to Rs. 15,000/- (fifteen thousand)depending on the grant amount,shall be remitted along with the application. In case of extension of approval additional fees of Rs. 2500/- shall be remitted.
5. BVDUCON, Pune-ECMembers shall commit to spending a minimum of 2 days in a year which includes (4/6 hrs. for each meeting) on meetings for ethical review and additional time needed for reviewing proposals and visiting projects. All Members, irrespective of whether they are appointed as primary orsecondary reviewers for specific proposals, shall be required to read all protocols sent to them and participate in the discussion during the meeting for ethical review to ensure that they conform to the guidelines used by the BVDUCON, Pune-EC. The only exception is for any Member with a conflict of interest with a particular proposal.
6. All Members shall be expected to allocate the required time for

meetings as per the agreed annual calendar of the meetings. If, for some unavoidable reasons, a Member is not able to attend the meeting, he/she should give prior intimation to Member Secretary at the earliest so as to make arrangements for his/her substitution if required. The Member shall communicate to the Member Secretary the review report with respect to the proposals allocated for review in advance before the meeting.

7. BVDUCON, Pune-ECMembers should attend at least one of the twomeetings in the year in person. He/ she can attend other meetings from their own location (other than the location of the meeting) through a telephonic conference or online conferencing mode. The Member shall promptly make arrangements to send scanned/e mailed/ printed copies of any documentation that shall be required during such a process. However, the quorum requirement will be met by committee Members being present in person during the BVDUCON, Pune-ECmeeting.
8. The EC shall ensure ethical conduct of research by the investigator team.
9. 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.

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

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

12. 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.
13. The EC should carry out monitoring visits at study sites as and when needed

VIII. Confidentiality

1.All Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of EC. The Members should not discuss matters related to BVDUCON, Pune-ECdeliberations with anyone other than BVDUCON, Pune-ECMembers.

IX Conflict of Interest

1.Conflict of interest(s), if any, should be declared by Members of the BVDUCON, Pune-ECat the beginning of every meeting. As a rule, any

Member who is directly associated with a research proposal must recues themselves from discussions and decisions related to that particular protocol.

2.An example of a conflict of interest would be when a Member of the BVDUCON, Pune-ECis also the PI/research team Member of the study of which the proposal is being considered by the EC.

3. All members shall sign the form for conflict of interest & confidentiality.

X. Criteria for selection of members

1. Members will be selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.

2.Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.

3.New members will be identified according to the requirement i.e. as per the composition specified in table 1 of this SOP and provided that the potential member fulfils the conditions of appointment as defined in this SOP.

4.Members to be appointed on the EC should be willing to fulfill the EC requirements as

a. Providing a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines,
b. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member,
c. Sign a confidentiality and conflict of interest agreement/s,
d. Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
e. Be committed and understanding to the need for research and for imparting protection to research participants in research.

XI. Resignation / Replacement procedure

1.A Member can be replaced in the event of death; resignation; long-term non availability; inability to attend/ participate in even one meeting during the year; or if his/her actions are not commensurate with the responsibilities of the BVDUCON, Pune-ECmembership as judged by a 2/3rd majority of the BVDUCON, Pune-ECMembers.

2.A member can tender resignation of his office of membership from

the EC to the Principal through the Chairperson after serving one month advancenotice.

3.During the term, Principal in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/or there is long period of (member) nonavailability.

4.Each member is required to sign the declaration and confidentiality agreement regarding EC activities

XII. Quorum requirements

1.A minimum of 5 Members are required to compose a quorum.

2.The quorum should include both medical, Nursing or/and non-technical members like lay person/ Legal expert/ Bio-statistician

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

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

5.All decisions should ideally be taken in meetings except in case of expedited review required in special circumstances.

6.No decision is valid without fulfillment of the quorum.

XIII. Conduct of BVDUCON, Pune-EC meetings

1.Chairperson

The Chairperson shall conduct all meetings of the BVDUCON, Pune-EC. In the absence of the Chairperson, an alternate Chairperson shall be elected by the Members present who shall conduct the meeting.

2.Secretary

The Member Secretary is responsible fororganizing the meetings, maintaining the records and communicating with all those concerned and shall maintain a copy of the minutes/proceedings of the meetings prepared after approval by the Chairperson, before communicating the same to the researchers. He/she shall issue decision notices to the research team whose project(s) has/have been reviewed after obtaining approval from the Chairperson within 2 weeks of the BVDUCON, Pune-ECmeeting.

All BVDUCON, Pune-ECrecords will be maintained by the secretary for a period of 5 years from the date of the end of the project.

XIV. Independent consultants

1.The BVDUCON, Pune-ECmay call upon such subject experts as independent consultants who may add or provide or valuable special review of selected research protocols, if need be.

2. 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 minorities. They are required to give their specialized views but do not take part in the decision making process of the EC.

3. They can join meetings online during pandemic situations.

XV. Application Procedures

a. Who can apply :

1.Faculty members, Post graduate and doctoral students/scholars of BVDUCON, Pune

2.Staff & Faculty members of any institute of Bharati Vidyapeeth (Deemed to be University), Pune, India who wish to do Nursing Research.

3.Independent researchers affiliated to Non-Government Organizations [NGOs], laboratories and organizations in the field of life science and who wish to conduct clinical research regarding Nursing.

b.Application details:

1.All proposals should be submitted in the prescribed application form, the details of which are given under heading Documentation Point number XVI.

2.All relevant documents should be enclosed with the application form.

3.The application form in the prescribed format and duly signed by the Principal Investigator (PI) (and Co-investigators/ Collaborators, where appropriate) along with all relevant documents should be electronically submitted to the BVDUCON, Pune-ECSecretary at least **3 (three)** weeks before the date of the BVDUCON, Pune-ECmeeting.

4.The date of the meeting shall be intimated to the researcher/PI. On that day, the PI or person designated by PI will have to make an oral presentation to the BVDUCON, Pune-ECand take questions for clarifications. Presentations over Skype or oral presentations

through conference mode are also acceptable. He/she will then leave the room while the proposal is being discussed by the BVDUCON, Pune-EC.

5.For the external agencies a prescribed fee of Rs. 5,000/- to Rs. 15,000/- depending on the grant amount,shall be remitted along with the application. In case of extension of approval additional fees of Rs. 2500/- shall be remitted.

6.The decision of the BVDUCON, Pune-ECshall be communicated in writing to the PI/researcher. If any revision is to be made in the proposal, the revised document should be submitted electronically within a stipulated period of time as specified in the communication or before the next meeting.

XVI. Documentation

All Research proposals (14 copies along with soft copy) shall be submitted along with the information and documents as specified below.
For a thorough and complete review, all research proposals should be submitted with the following documents:
1.Name of the applicant with designation.

2.Name of the Institute/ Hospital / Field area where the proposed research is to be conducted.

3.Detailed protocol of the proposed research.

4.Ethical issues in the study and plans to address these issues.

5.Proposal should be submitted with all relevant enclosures like Performa, case report forms, questionnaires, follow - up cards, etc.

6.Informed consent process, including patient information sheet and informed consent form/ assent in local language(s).

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

8.Curriculum vitae of all the investigators with relevant publications in last five years.

9.Any regulatory clearances required.

10.Sponsor(s) and source(s) of funding; budget of the study.

11.Other financial issues including those related to insurance.

12.An agreement to report Serious Adverse Events (SAE) to

BVDUCON, Pune-EC.

13.Statement of conflict(s) of interest, if any.

14.Agreement to comply with the relevant national and applicable international guidelines, as applicable.

15.A statement describing any compensation for study participation (including expenses &access to medical care) to be given to research participants, a description of the arrangement for indemnity, if applicable (in study-related injuries), a description of the arrangements for insurance coverage for research participants, if applicable, all significant previous decision(e.g. those leading to a negative decision or modified protocol) by other ethics boards or regulatory authorities for the proposed study (whether in the same location or elsewhere) & indication of the modification (s) to the protocol made on that account. The reasons for negative decisions should be provided.

16.Plans for publication of results-positive or negative- while maintaining the privacy and confidentiality of the study participants.

Any other information relevant to the study.

XVII Review procedures

1.The meeting of the BVDUCON, Pune-EC will be held on periodic intervals& 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 workload.
2.The proposals should be sent to the BVDUCON, Pune-ECat least 3 weeks in advance of schedule meeting.

3.The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review

4.The secretariat of the BVDUCON, Pune-ECcan allocate proposals to 1-2 primary reviewers to prepare a detailed evaluation which can then be discussed by all Members at the meeting if necessary.

5.The BVDUCON, Pune-ECwill take care that special attention is given to the informed consent process, documentation, and the suitability and feasibility of the protocol.

6.Researcher/PI should make an oral presentation to the BVDUCON, Pune-ECand take questions for clarifications.

7.Researchers shall be invited to offer clarifications if need be.

8.Independent consultants/Experts shall be invited to offer their opinion on specific research proposals if and when needed.

9.Decisions shall be taken by consensus after discussions.

10.The decisions shall be recorded and signed by members present at the meeting and Chairperson will provide approval in writing.

11.All Members of the BVDUCON, Pune-EC, including those who were not present at the meeting, will be informed of the decision via email.

A Expedited review

1.In exceptional circumstances an application requires urgent review and BVDUCON, Pune-ECapproval (e.g. an urgent call for proposal which cannot wait for the next quarterly meeting) in such cases expedited review may also be taken up after consideration of the circumstances by the Chairperson and the Member Secretary.

2.The concerned PI should approach the Chairperson through the Member Secretary and should be able to explain and convince the chairperson the need for an expedited review.

3.A sub-committee will then be convened by the Chairperson to review the proposal and make a decision. Approval given in such situations will be provisional and subject to ratification at the next full committee meeting.

4.Expedited reviews are considered acceptable in minimal risk studies where minimal risk is defined as ―the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

B Exemption fromreview

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

1.Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Researchconductedondataavailableinthepublicdomainforsystematicreviews or meta-analysis;

3.Observation ofpublic behavior when information is recorded without
anylinkedidentifiersanddisclosurewouldnotharmtheinterestsofthe observedperson;

C Full committee review

Allresearchproposalspresentingmorethanminimalriskthatarenotcove red under exempt or expedited review should be subjected to full committee review, some examplesare;

1.Research involving vulnerable populations, even if the risk isminimal;
2. Researchwithminorincreaseoverminimalrisk
3.Research during emergencies and disasters either through an expedited
review/scheduledorunscheduledfullcommitteemeetings.Thismay be decidedbyMemberSecretarydependingontheurgencyandneed;
4.Priorapprovalofresearchonpredictableemergenciesordisasters beforethe actual crisis occurs for implementation later when the actual emergency or disaster occurs.

XVIII Aspect considered during review of research proposal
I.

1.Scientific design and conduct of the study.

2.Approval of appropriate scientific review Boards.

3.Examination of predictable risks/harms.

4.Examination of potential benefits.

5.Procedure for selection of subjects in methodology including inclusion/ exclusion/ withdrawal criteria and other issues like advertisement details. Criteria for withdrawal of patients, suspending or terminating the study

6.Management of research related injuries, adverse events and serious adverse events.

7.Compensation provisions.

8.Patient information sheet and informed consent form in local language.

9.Protection of privacy and provision of confidentiality.

10.Involvement of the community, when and where necessary.

11.Plans for data analysis and reporting, along with safety and quality assurance report(s).

12.Competence of investigators, research and supporting staff.

13.Facilities and infrastructure of study sites.

XIX. Decision-making

1. Members shall discuss the various issues before arriving at a consensus.

2. A Member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises andthis should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

3. Decisions shall be made only in meetings when quorum is complete.

4. Only BVDUCON, Pune-EC Members can make decision(s). The expert consultants shall only offer their opinions.

5. Decision(s) may be to a) approve, b) reject or c) conditional acceptance subject to receipt of further information/modifications. . Specific suggestions for modifications and reasons for rejection should be duly communicated to the researcher.

6. In cases of conditional decisions, clear suggestions for revision and the procedures for having the application re-reviewed, if deemed necessary, should be specified.

7. Modified proposals may be reviewed by an expedited review by the Chair person and he/ she can invite other Members to examine the revised application and if the BVDUCON, Pune-ECrecommendations have been adhered to the applicant will be given the required approval by the Chairperson.

XX. Communicating the decision

1.Decision(s) taken by the BVDUCON, Pune-ECshall be duly communicated by the Member Secretary in writing to all the Members of the BVDUCON, Pune-ECand those concerned directly/ indirectly with such decisions.

2.Suggestion(s) for modifications in the proposal/ protocol, if any, should be duly communicated to the researcher by the BVDUCON, Pune-EC.

3.Reason(s) for rejection of the proposal/ protocol should be duly informed to the researcher(s) with reasons for the same.

4.The schedule/ plan of ongoing review by the BVDUCON, Pune-

ECshould be communicated to the Principal investigator (PI).

XXI. Follow up procedures for approved proposals by PI/Sponsor

1.All ongoing projects that have been given ethical approval have to submit their annual reports to the BVDUCON, Pune-ECat 12 months after approval was granted. These would then be tabled at the next BVDUCON, Pune-ECmeeting.

2.Final report should be submitted at the completion of the study.

3.All SAEs (severe adverse events) and the action interventions undertaken for the same should be intimated to the BVDUCON, Pune-ECChairperson and/ or Member Secretary, ideally immediately, and within 72 hours of occurrence.

In the event of non-availability of the Chairperson and/or the Member Secretary, the same shall be notified to other Member(s) of the BVDUCON, Pune-EC, which shall be notified to the Chairperson and/or the Member Secretary) not exceeding one week after the reporting of the SAE by the researcher/research team member. If case of delay in reporting the SAE by the researcher/research team member occurs, prompt and appropriate action against the researcher shall be initiated by the BVDUCON, Pune-EC. It can even be decided to suspend/ terminate the project as decided by the BVDUCON, Pune-EC. The decision of the BVDUCON, Pune-ECshall be final.

4.All protocol deviation(s), if any, should be promptly informed with adequate justifications for the same to the BVDUCON, Pune-ECChairperson. The Chairperson will then decide if fresh approval is indicated. Any major deviations (such as change in design, target sample, inclusion of a new intervention component) will require resubmission for fresh approval.

5.Minor amendment(s) to the protocol (such as increasing or decreasing number of people to be interviewed) do not need fresh approval from the BVDUCON, Pune-ECthe chairperson and secretary can give the necessary permission for inclusion of the change to the original protocol. All such information should be recorded and communicated to the BVDUCON, Pune-ECthrough the annual reports.

6.Premature termination/ suspension of study should be duly notified with appropriate and adequate justifications along with the summary of the data obtained so far.

7. Any change of investigator(s) / site(s)/ sponsor(s) / funding(s) should be duly informed to the BVDUCON, Pune-ECwithin one week failing which appropriate and prompt action against the investigator

shall be initiated by the BVDUCON, Pune-EC.

XXII. Appeal procedures

This procedure is
1.Where the BVDUCON, Pune-EChas rejected an application for ethics approval (for reasons other than the application being incomplete) and the researcher applicant wishes to appeal.

2. Where the BVDUCON, Pune-EChas approved an application for ethics approval subject to some changes being made and the researcher disagrees with the proposed changes. In this case, before making a formal appeal, the researcher should initially confer with the Chairperson for clarification of the reasoning of the BVDUCON, Pune-EC.

After this consultation, if the researcher is not satisfied then s/he can make a formal appeal as outlined below.

1. If the Researcher wishes to appeal a decision made as part of the approval process, s/he must notify the Chairperson of the BVDUCON, Pune-ECthrough the Member Secretary. The appeal should be in writing and must be sent via post or email within fourteen days of being notified of that decision.

2. The Chairperson can appoint a committee independent of the BVDUCON, Pune-ECwho will then review the application and give recommendations to the EC.

3. The membership of the Panel shall be at the discretion of the BVDUCON, Pune-ECChairperson.

4. Once the panel has reached its decision, the panels Chairperson can give the recommendations of the committee to the BVDUCON, Pune-ECand based on the recommendations the BVDUCON, Pune-ECcan make an amended decision. This decision cannot be appealed against, using the procedure described above.

XXIII. Record keeping and archiving at the office of BVDUCON, Pune-EC

The BVDUCON, Pune-ECshall be required to maintain the following records for a period of at least 5 years (or as the quorum deems it necessary). The Member Secretary shall be responsible for the same.

1. Curriculum Vitae (CV) of all Members of EC.

2. Copy of all study protocols with enclosed documents, progress reports, and reports on SAEs, protocol deviations and any further documents/reports that the BVDUCON, Pune-ECmay require the researcher to provide.

3. Each application will be provided with a unique ID number which will be maintained for all documents related to that particular project/ application. All documents related to a particular project will be saved in hard as well as soft copy in a designated folder. The folder will be pass-word protected and accessible only to the BVDUCON, Pune-ECMembers.All hard copies will be kept under lock and key.

4. Minutes of all meetings duly signed by the Chairperson of the EC. The minutes of meetings shall be noted down by the personal secretary (PS) and consequently typed. It is the duty of the Member Secretary to duly maintain the typed minutes prepared by the PS.

5. A copy of all existing relevant national and international guidelines/updates/amendments on research ethics and laws amendments.

6. A copy of correspondence with Members, researchers and other regulatory bodies.

7. Annual and final report(s) of all the approved projects.

8. All publications related to a particular proposal should be submitted to the BVDUCON, Pune-ECfor record purposes. Ethics approval should be acknowledged in all research manuscripts arising from the approved study.

XXIV Updating BVDUCON, Pune-EC members

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1. Any relevant updates/ guidelines in the processes of the BVDUCON, Pune-ECshall be brought to the immediate attention of all Members.
2. Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review by being updated with the latest development in this milieu.

XXV. Terms of reference for BVDUCON, Pune-EC

Terms of reference will be maintained in the office of BVDUCON, Pune-EC. This includes

a. MembershipRequirements

b. Terms of Appointment with reference to the duration of theterm,

c. The policy for removal, replacement, resignationprocedure,

d. Frequency of meetings,and

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

1.All EC members shall be provided hard as well as soft copy of latest version of SOP.

2.All members shall be trained on the SOPs.

3.SOP shall be made available in the secretariat of the EC.

4.The EC shall be registered with Department of Health Research

5.The Principal, Bharati Vidyapeeth (Deemed to be University), College of Nursing, Pune shall appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter.

6. The duration of appointment of the BVDUCON, Pune-ECMembers shall be initially for a period of **3** years. A Member cannot be on the BVDUCON, Pune-ECfor more than two consecutive terms.

7. At the end of the stipulated 3 years, as the case may be, the committee shall be reconstituted, and new Members shall replace Members who wish to discontinue or need to be replaced. New members should regularly be invited to join the BVDUCON, Pune-ECso that we have enough members to replace ones that have to step down.

8. All Members shall be paid remuneration per meeting as well as the cost of travel for participation in the meetings as per the university rules.

XXVI Special Considerations/ Protection of vulnerable population

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

Individuals may be considered to be vulnerable if they are:
• Socially, economically or politically disadvantaged and therefore susceptible to being exploited;
• incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for

example people who are unconscious, differently abled;
• Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
• Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

ICMR guidelines as applicable will be followed for protection of vulnerable population.

Following duties will be followed by stakeholders while dealing with vulnerable participants like woman in special situations, children, sexual minorities & sex workers, individual with mental illness, terminally ill patients etc.

Table No. 2 Obligations/duties of stakeholders

Sr. No.	Stakeholders	Obligations / duties
1	Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • 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.
2	Ethics Committees	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

		• ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.
3	Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

A Consent of parent/LAR

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.

2. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

3. Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.

4. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.

5. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate

mechanism to safeguard the interests of the child.

6. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.

7. Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

8. Assent
   Content of the assent form has to be in accordance with the developmental level and maturity of the children to be enrolled and explained while considering the differences in individual understanding. The language of the assent form must be consistent with the cognitive, social and emotional status of the child. It must be simple and appropriate to the age of the child. Points to be included in the assent form are as given below:
   - an explanation about the study and how it will help the child;
   - an explanation of what will be done in the study, including a description of any discomfort that the child is likely to feel;
   - the contact information of the person whom the child can approach if she/he needs an explanation; and
   - A paragraph emphasizing that the child can refuse to participate in the study and if she/he chooses to do so, the treatment at the centre will not be compromised.

B Considerations for assent

1. There is no need to document assent for children below 7 years of age.
2. For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
3. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
4. Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult

should be taken and recorded with the approval of the EC, for example, in behavioral studies in IV drug users where parental consent may not be possible.

XXVII SOPs to be followed during COVID-19 Pandemic & emergency situations
(Annexure – A)

References-

1. National Ethical Guidelines For Biomedical And Health Research Involving Human Participants 2017
2. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During COVID-19 Pandemic
3. Human Ethics guidelines, www.icmr.nic.in

Standard operating Procedures, Human Ethics Committee, Tata Memorial Centre, Tata Memorial Hospital, https://tmc.gov.in/research/pdf/TMC-HEC-SOP.pdf

4. Standard operating Procedures, Human Ethics Committee, Sangtha, Goa, http://sangath.com/images/file/SOPs_v4_15_april_2012.pdf
5. http://www.sgpgi.ac.in/sop/main.htm

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(Annexure – A)

GUIDELINE FOR ETHICS COMMITTEE DURING COVID-19 PANDEMIC & EMERGENCY SITUATIONS

I. GENERAL ETHICAL ISSUES

1. Benefit risk assessment-The EC shall decide about the type of review required (exempted,expedited,full committee) based on type of risk involved.

2. Privacy Confidentiality

Information related to COVID-19 infection may be highly sensitive in nature with a lot of scope for stigmatization, discrimination, violence etc.

EC shall ensure Maintaining confidentiality of research related data and its publication to protect privacy of individuals and avoid any discrimination against them.

3. Compensation for research –related harm

a. Research participant who suffer direct physical, psychological, social, legal or economic harm as a result of participating in the research are entitled to free health care and referrals needed. However, for research related serious adverse events (SAE), appropriate financial compensation and insurance coverage will be provided as per norms.

b. Sponsor shall include insurance coverage/other provision within budget. In investigator initiated research, investigator/institution must provide through insurance, corpus funds or grants.

c. SAEs should be reported to EC (including on non-working days) within 24 hours and report of SAE relatedness (causality assessment) within 14 days for EC review regarding quantum and type of assistance.

4. Collaboration in research

a. An appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance (addressing issues of confidentiality, sharing of data, joint publications, etc.) should be made between the Institutes.

b. Biomedical and health research proposals involving foreign

assistance and/or collaboration be submitted to Health Ministry's Screening Committee (HMSC) for approval before initiation.

5. Public health and social behavioral research

1. The social distancing norms may not facilitate conventional methods of data collection & alternative study designs may be required such as online or remote methods to conduct interviews, focus groups, surveys or questionnaires.

2. EC will ensure the confidentiality from researcher while using the electronic methods of data collection.

3. Stakeholders are to consider the fact that technological requirements of health study design may exclude participants without access to the technology.

4. For obtaining quality data, verification of identity of research participants is required. However, exchanging confidential information electronically is prone to security threats. The privacy & security features of the virtual tool will be assessed by EC.

5. Collection of identifying information, GPS location, IP address tracking, etc. should be reviewed by EC on case-case basis.

6. Ethics Review Procedure

a. Ethics committee shall ensure that all COVID-19 related research (all clinical trials as well as biomedical and health research) be registered on Clinical Trial Registry of India (CTRI) and seek approvals as per relevant guidelines and applicable regulations.

b. Member Secretary shall categories proposals into exempt/expedited/ or full review category as per National Ethical Guidelines and plan next steps for fast track review.

c. Research during emergencies can be reviewed through expedited review/unscheduled full committee meetings on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review can follow whenever next possible.

d. Measures such as virtual or teleconference/web conferences should be attempted and face-to-face meetings can be avoided to observe social distancing norms.

e. In exceptional and emergency situations, preliminary research procedures including but not restricted to data/ biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.

7. Special situations

a. Registered Independent ECs can review protocols of researchers who have no institutional attachments or of institutions without their own ethics committees.

b. Electronic documents may be accepted for review and timelines shortened for accelerated procedures.

c. During the review process, the Ethics Committees should consider the following:

1. If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally/ use electronic methods to document andrecord.

2. Due to inability of the participant to attend the site (for e.g., social distancing), the contact/communication can be made via phone, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation.

3. In an ongoing study, if the designated PI is indisposed for a period, she/he may need to delegate parts of her/his duties temporarily to others & the same should be documented & reported to EC at the earliest.

4. EC members present during the virtual meeting should decide through consensus or cast online vote expressing their decision. Any disagreement to be recorded with reasons.

5. Meeting could be digitally recorded (audio/video) with permission of members and secretariat is responsible to note the attendance/ participation in the online meeting.

8.Informed Consent

a. Obtaining valid informed consent in humanitarian emergencies such as COVID-19 is a challenging due to practical difficulties in reaching out to a patient, who may be in a COVID ward, isolation or quarantine facility.

b. Needful procedure will be followed as discussed in National Ethical Guidelines for involving children (assent) or legally

authorized representative (LAR) in case a participant is incompetent (medically or legally), illiterate participant/ LAR should be witnessed by an impartial literate witness.

c. The Informed Consent Document (ICD) has two parts- patient/ participant information sheet (PIS) & the Informed Consent Form (ICF) & can be prepared preferably utilizing electronic formats or plan methods to obtain consent maintaining adequate social distancing.

d. Technology should be utilized to prepare interactive formats & using electronic tools such as text, graphics, audio, video, podcasts etc. to explain information related to study & to electronically document informed assent/ consent the same.

e. Electronic methods must be reviewed & approved by the EC.

f. Process can be documented through audio or video recording if required.

9. Waiver ofConsent

For seeking waiver of consent, the researchers should give the rationale justifying the waiver which EC can approve a waiver after careful discussion in the following situations

a. Research cannot practically be carried out without the waiver & the waiver is scientifically justified like, cluster randomization trials.

b. Retrospective studies, where the participants are de-identified or cannot be contacted.

c. Research on anonymized biological samples/ data.

d. Certain types of public health studies/ surveillance programs/ program evaluation studies.

e. Research on data available in the public domain.

f. Research during humanitarian emergencies & disasters, when the participants may not be in a position to give consent.

g. When consent of the participants/ LAR/ Assent is not possible due to the emergency situation, informed consent can be administered at a later stage, when the situation allows for it, & if

it is so envisaged, prior permission must be obtained from the EC.

10. Vulnerability

Vulnerable persons are individuals/ belonging to certain groups of persons who are relatively or absolutely in capable of protecting their own interests such as:

1. COVID-19 patients may be additionally vulnerable of being stigmatized due to the contagious nature of the disease. Also at risk are health care workers in COVID-19 hospitals including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers etc.
2. Socially, economically or politically advantaged individuals such as the stranded migrant workers who are susceptible to being exploited.
3. Incapable of making a voluntary informed decision or whose autonomy is compromised temporarily or permanently.
4. EC will ensure that researcher to address the needs of participants & justify inclusion of vulnerable persons.
5. Benefits & risks are carefully determined & the risk minimization strategies are examined.
6. There is no coercion, force, undue influence, threat or misrepresentation nor incentives.
7. The Informed consent process is conducted in a respectful manner.

References

1. National Ethical Guide lines for Biomedical & Health Research involving human participants, New Delhi: Indian Council of Medical Research; 2017. Available from: (http://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf).
2. Department of Health Research (DHR), MOHFW, Government of India, National Ethics Committee Registry for Biomedical and Health Research (NECRBHR). Available from https://naitik.gov.in/DHR/Homepage

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References

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2. Department of Health Research (DHR), MOHFW, Government of India, National Ethics Committee Registry for Biomedical and Health Research (NECRBHR). Available from https://naitik.gov.in/DHR/Homepage

Chairman

Dr. S. R. Agarkhedkar