

BHARATI VIDYAPEETH
(Deemed To Be University)
DENTAL COLLEGE & HOSPITAL, PUNE
INSTITUTIONAL ETHICS COMMITTEE



STANDARD OPERATING PROCEDURES

Institutional Ethics Committee

Bharati Vidyapeeth (Deemed to be University) Dental College and Hospital, Pune

1. 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 Dental College and Hospital Pune– Institutional Ethics Committee (BVDUDC&H-IEC)** 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 BVDUDC&H, Pune. These SOPs are based on the ICMR ethics guidelines for biomedical research.

2. Role of BVDUDC&H- IEC

- The BVDUDC&H- Pune- IEC shall review and monitor all types of research proposals conducted in BVDUDCH, Pune 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.
- The BVDUDC&H- Pune- IEC shall 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.
- The BVDUDC&H- Pune- IEC shall 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.

- All proposals shall be reviewed before the start of the study. After due clearance from the BVDUDC&H- Pune- IEC the 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 to the ethics committee.

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

- 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.

- The BVDUDC&H- Pune- IEC shall 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.

3. Membership Requirement

Composition of the BVDUDC&H- Pune- IEC- As per ICMR guidelines,

- The BVDUDC&H- Pune- IEC shall be cross-disciplinary and multisectoral in composition.
- The Board shall consist of 7-15 members.

- A minimum of 6 persons shall be required to constitute a quorum without which the holdings and businesses of the BVDUDC&H- Pune- IEC shall stand adjourned until such a number is available to conduct the same.
- The Chairperson of the Board shall be from outside the Institution i.e. Bharati Vidyapeeth Deemed University, Dental College & Hospital- Pune. BVDUDC&H- Pune- IEC 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.
 - The Member Secretary shall be from BVDUDC&H- Pune- IEC and shall coordinate the secretariat of the committee in all its dealing.

Guided by the ICMR guidelines, the composition of the BVDUDC&H- IEC shall thus be as follows:

- Chairperson from outside BVDUDC&H- Pune- IEC
- Member Secretary from BVDUDC&H- Pune- IEC
- At least 4 Members from different specialties/disciplines as specified below:

Health scientists / researchers: from Dentistry or Bio- medicine

Clinicians / health practitioners: from Dentistry or Bio-medicine

Legal/ethics expert

Social scientist / philosopher/ writer / priest

Lay person (representative of community)

- At least half of the committee Members will be non-BVDUDC&H- Pune- IEC (not employed) and at least half of preferably more of the quorum would be constituted by external Members.

Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- New members will be identified according to the requirement i.e. as per the composition specified in section 6 b of this SOP and provided that the potential member fulfils the conditions of appointment as defined in of this SOP.

The following qualities are sought in members:

- Interest and motivation
- Time and effort
- Commitment and availability
- Experience and education
- Respect for divergent opinions
- Integrity and diplomacy

4. Authority under which the BVDUDC&H- Pune- IEC is constituted

- The Head of the Institute
- Bharati Vidyapeeth Deemed University Dental College and Hospital, constituted the Institutional Ethics Committee in order to ensure that research on human subjects, using research methodology that meets international and local regulations, ethical standards and is consistent with principles of GCP.

5. Offices

The BVDUDC&H- Pune- IEC will have the following office bearers who have the expertise and professional qualifications to review the proposals.

Chairperson

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

Member Secretary

- The Member Secretary is responsible for organizing 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 BVDUDC&H- IEC meeting.
- All BVDUDC&H- Pune- IEC records will be maintained by the secretary for a period of 5 years from the date of the end of the project.

BVDUDC&H- Pune- IEC Administrative Staff: Working Rule

- There will be administrative officer/s and attendant/s /helper/s who will help the Chairperson and Member Secretary in executing functions of the IEC.
- Additional staff may be appointed and duties assigned; as and when necessary by the IEC.

Duties of the administrative officer/s/staff

- Correspondence with the IEC members and external experts
- Correspondence with the investigators
- Pre and post arrangements of IEC meetings
- Preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files.
- The administrative staff will report to the Chairperson and/or Member Secretary.

- The office timing for the administrative staff will be as per BVDUDC&H-Pune, rules & regulations.
- The administrative staff will avail leave as per BVDUDC&H-Pune, norms.

6. Roles and responsibilities of BVDUDC&H- Pune- IEC Members and terms of membership:

6 a. Roles and Responsibilities

- All Members of the BVDUDC&H- Pune- IEC shall be required to undertake the review of research proposals, participate in meetings and businesses of the BVDUDC&H- Pune- IEC and monitor any ongoing research.
- BVDUDC&H- Pune- IEC Members shall commit to spend 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 or secondary 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 IEC. The only exception is for any Member with a conflict of interest with a particular proposal as noted below.
- 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.
- BVDUDC&H- Pune- IEC Members should attend at least two of the three meetings 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 BVDUDC&H- Pune- IEC meeting.

6b. Conditions of appointment:

- The duration of appointment of the BVDUDC&H- Pune- IEC Members shall be initially for a period of **3** years. A Member cannot be on the BVDUDC&H- Pune- IEC for more than two consecutive terms.
- All members shall sign the ‘**Confidentiality Agreement**’ and the ‘**Agreement for Declaration of Conflict of Interest**’.

6c. Resignation / Replacement procedure

- 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 BVDUDC&H- Pune- IEC membership as judged by a 2/3rd majority of the BVDUDC&H- Pune- IEC Members.
- The member shall communicate his or her resignation preferably in writing to the IEC.

6d. Policy regarding training of new and existing committee members:

- It is mandatory for all new members to attend the training program of “**Good Clinical Practices**” guidelines and provide the certificate of same.
- Any relevant updates/ guidelines in the processes of the BVDUDC&H- Pune- IEC shall be brought to the immediate attention of all Members. Members shall be encouraged to attend national and international training programs in research and ethics for maintaining quality in ethical review by being updated with the latest development in this milieu.

6e. Confidentiality

All Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of IEC.

The Members should not discuss matters related to BVDUDC&H- Pune- IEC deliberations with anyone other than other BVDUDC&H- Pune- IEC Members. All personal copies of documents and emails related to the proposal should be destroyed immediately. (**Annexure I**)

6 f. Conflict of Interest

- Conflict of interest(s), if any, should be declared by members of the BVDUDC&H- Pune- IEC members. As a rule, any member who is directly associated with a research proposal must avoid themselves from discussions and decisions related to that particular protocol. An example of a conflict of interest would be when a Member of the BVDUDC&H- Pune- IEC is also the PI/research team Member of the study of which the proposal is being considered by the IEC.
- All the IEC members shall sign the agreement of 'Declaration of the Conflict of Interest' (**Annexure II**) at the time of joining the committee.
- The member who has a conflict of interest shall declare the same in the beginning of meeting in writing to the Chairman of the IEC.

7. Quorum requirements

- A minimum of 6 Members are required to compose a quorum.
- All decisions should ideally be taken in meetings except in case of expedited review required in special circumstances (see pt.11.3).

8. Independent consultants

The BVDUDC&H- Pune- IEC may call upon such subject experts as independent consultants who may add or provide valuable 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 minorities. They are required to give their specialized views but do not take part in the decision making process of the IEC.

9. General Application Procedures:

9.1 Who can apply:

- Faculty members, Post graduate and doctoral students/scholars of BVDUDC&H- Pune- IEC.
- Staff and Faculty members of any institute of Bharati Vidyapeeth Deemed University, Pune, India who wish to do Dental research.
- Independent researchers affiliated to Non-Government Organizations [NGOs], laboratories and organizations in the field of life science and who wish to conduct research regarding Dentistry.

9.2 Application details:

- All proposals should be submitted in the prescribed application form, the details of which are given under heading Documentation Point number 11.
- All relevant documents should be enclosed with the application form.
- 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 BVDUDC&H- Pune- IEC Secretary at least 2 weeks before the date of the BVDUDC&H- Pune- IEC meeting.
- 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 BVDUDC&H- Pune- IEC and 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 BVDUDC&H- Pune- IEC.
- For the external agencies a prescribed fee of Rs. 5,000to 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.

- The decision of the BVDUDC&H- Pune- IEC shall 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.

10. Documentation

For a thorough and complete review, all research proposals should be submitted with

the following documents:

- Name of the applicant with designation.
- Name of the Institute/ Hospital / Field area where the proposed research is to be conducted.
- Detailed protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
- **Informed consent process, including patient information sheet and informed consent form/ assent in local language(s).**
- 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.
- Curriculum vitae of all the investigators with relevant publications in last five years.
- Any regulatory clearances required.
- Sponsor(s) and source(s) of funding; budget of the study.
- Other financial issues including those related to insurance.
- **An agreement to report Serious Adverse Events (SAE) to IEC.**
- **Statement of conflict(s) of interest, if any.**
- Agreement to comply with the relevant national and applicable international guidelines, as applicable.

A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (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) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

- 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.

11. Review procedures:

11.1 Conduct of review:

The BVDUDC&H- Pune- IEC will take care that special attention is given to the informed consent process, documentation, and the suitability and feasibility of the protocol.

- The secretariat of the BVDUDC&H- Pune- IEC can 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.
- Researcher/PI should make an oral presentation to the BVDUDC&H- Pune- IEC and take questions for clarifications.
- Researchers shall be invited to offer clarifications if need be.
- Independent consultants/Experts shall be invited to offer their opinion on specific research proposals if and when needed.
- Decisions shall be taken by consensus after discussions.

- The decisions shall be recorded and signed by members present at the meeting and Chairperson's will provide approval in writing.
- All Members of the IEC, including those who were not present at the meeting, will be informed of the decision via email

11.2 Element(s) of review

- Scientific design and conduct of the study.
- Approval of appropriate scientific review Boards.
- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects in methodology including inclusion/ exclusion/ withdrawal criteria and other issues like advertisement details.
- Management of research related injuries, adverse events and serious adverse events.
- Criteria for withdrawal of patients, suspending or terminating the study.
- Compensation provisions.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and provision of confidentiality.
- Involvement of the community, when and where necessary.
- Plans for data analysis and reporting, along with safety and quality assurance report(s).
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure of study sites.

11.3 Expedited review

In exceptional circumstances an application requires urgent review and BVDUDC&H- Pune- IEC approval (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. The concerned PI should approach the Chairperson through the Member Secretary and should be able to explain and convince the chair the need for an expedited review. 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. 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.¶ (*United States Department of Health and Human Services Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects*)

11.4 Decision-making procedures

- Members shall discuss the various issues before arriving at a consensus.
- 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.
- Decisions shall be made only in meetings when quorum is complete.
- Only BVDUDC&H- Pune- IEC Members can make decision(s). The expert consultants shall only offer their opinions.
- 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.
- In cases of conditional decisions, clear suggestions for revision and the procedures for having the application re-reviewed, if deemed necessary, should be specified.

- 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 BVDUDC&H- Pune- IEC recommendations have been adhered to the applicant will be given the required approval by the Chairperson.

12. Communication within the BVDUDC&H- Pune- IEC and those concerned

Here with

- Decision(s) taken by the BVDUDC&H- Pune- IEC shall be duly communicated by the Member Secretary in writing to all the Members of the BVDUDC&H- Pune- IEC and those concerned directly/ indirectly with such decisions.
- Suggestion(s) for modifications in the proposal/ protocol, if any, should be duly communicated to the researcher by the IEC.
- Reason(s) for rejection of the proposal/ protocol should be duly informed to the researcher(s) with reasons for the same.
- The schedule/ plan of ongoing review by the BVDUDC&H- Pune- IEC should be communicated to the Principal investigator (PI).

13. Appeal Procedures

This procedure is

- i) Where the BVDUDC&H- Pune- IEC has rejected an application for ethics approval (for reasons other than the application being incomplete) and the researcher applicant wishes to appeal.
- ii) Where the BVDUDC&H- Pune- IEC has approved an application for ethics approval subject to some changes being made and the researcher disagrees with the proposed changes. In such a case, before making a formal appeal, the researcher should initially confer with the Chairperson for clarification of the reasoning of the IEC. After this consultation, if the researcher is not satisfied then she/he can make a formal appeal as outlined below.

- If the Researcher wishes to appeal a decision made as part of the approval process, s/he must notify the Chairperson of the BVDUDC&H- Pune- IEC through 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.
- The Chairperson can appoint a committee independent of the BVDUDC&H- Pune- IEC who will then review the application and give recommendations to the IEC.
- The membership of the Panel shall be at the discretion of the BVDUDC&H- Pune- IEC Chairperson.
- Once the panel has reached its decision, the panel Chairperson can give the recommendations of the committee to the BVDUDC&H- Pune- IEC and based on the recommendations the BVDUDC&H- Pune- IEC can make an amended decision. This decision cannot be appealed against, using the procedure described above.

14. Follow up procedures

- All ongoing projects that have been given ethical approval have to submit their **annual reports to the BVDUDC&H- Pune- IEC at 12 months after approval was granted.** These would then be tabled at the next BVDUDC&H- Pune- IEC meeting.
- Final report should be submitted at the completion of the study.
- **All SAEs (severe adverse events) and the action interventions undertaken for the same should be intimated to the BVDUDC&H- Pune- IEC Chairperson 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 IEC, 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 IEC. It can even be decided to suspend/ terminate the project as decided by the IEC. The decision of the BVDUDC&H- Pune- IEC shall be final.

- All protocol deviation(s), if any, should be promptly informed with adequate justifications for the same to the BVDUDC&H- Pune- IEC Chairperson. 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.
- Minor amendment(s) to the protocol (such as increasing or decreasing number of people to be interviewed) do not need fresh approval from the BVDUDC&H- Pune- IEC– the chair 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 BVDUDC&H- Pune- IEC through the annual reports.
- Premature termination/ suspension of study should be duly notified with appropriate and adequate justifications along with the summary of the data obtained so far.
- Any change of investigator(s) / site(s)/ sponsor(s) / funding(s) should be duly informed to the BVDUDC&H- Pune- IEC within one week failing which appropriate and prompt action against the investigator shall be initiated by the IEC.

15. For Vulnerable population:

15.a. For pregnant women, Fetus-

- The IEC will take precautions involving pregnant women and fetuses in the research with least possible risk and additional attention will be given to obtain informed consent.
- The IEC will ensure that women are not encouraged to discontinue nursing for the sake of participation in research.

15.b. For Children:

- The IEC require that adequate provisions are made for solicit the permission of each child's parent or guardian/ legally acceptable representative.
- Provisions are made in the protocol to obtain child's assent.
- The assent form will be designed with respect to his or her level of understanding.
- IEC will respect child's refusal to participate in the research.

16. Record keeping and Archiving

The BVDUDC&H- Pune- IEC shall 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.

- Curriculum Vitae (CV) of all Members of IEC.
- Copy of all study protocols with enclosed documents, progress reports, reports on SAEs, protocol deviations and any further documents/reports that the BVDUDC&H- Pune- IEC may require the researcher to provide.
- 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 BVDUDC&H- Pune- IEC Members. All hard copies will be kept under lock and key.
- Minutes of all meetings duly signed by the Chairperson of the IEC. 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.
- A copy of all existing relevant national and international guidelines/updates/amendments on research ethics and laws amendments.
- A copy of correspondence with Members, researchers and other regulatory bodies.
- Annual and final report(s) of all the approved projects.
- All publications related to a particular proposal should be submitted to the BVDUDC&H- Pune- IEC for record purposes. Ethics approval should be acknowledged in all research manuscripts arising from the approved study.

1. Updating BVDUDC&H- Pune- IEC Member


Any relevant updates/ guidelines in the processes of the BVDUDC&H- Pune- IEC shall be brought to the immediate attention of all Members. 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.

17. Remuneration to BVDUDC&H- Pune- IEC Members


- 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.

References-

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