APPLICATION TO THE BVDUDC&H-PUNE/INSTITUTIONAL ETHICS COMMITTEE FOR APPROVAL OF A RESEARCH PROJECT

(APPLICATION FORM FOR INITIAL REVIEW)

EC No……(For office use only)

Section A - Basic data

1. Administrative details

Name of Institute where research will be carried	
Name of Ethics Committee with registration number	Institute Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Dental College and Hospital, Pune. Ethics Committee Registration No. **EC/NEW/INST/2021/MH/0029** issued under New Drugs and Clinical Trials Rules, 2019
Principal investigator (Designation and Qualification, Department and Institution)	
Qualifications:	
Professional registration (Name of body, registration number)	
Address of PI for correspondence: (With email ID & phone number)	
Permanent address for future correspondence	
Project/Research Title	
Project/Research CTRI no. (mention NA-if not applicable)	
Guide/Co- investigator (Designation and Qualification, Department and Institution) CV of all investigators with publications in last 5 years (attach)	
Address of Guide/Co- investigator	
Sponsoring Organization (mention NA-if not applicable)	
Site contact details (address/ phone no of place where research work will take place)	

Date of application submission	

2. Funding Details and Budget

Total estimated budget:					
Self-funding	☐	Institutional funding	☐	Funding agency(specify)	☐

Section B – Research Related Information

3. Overview of Research

a. Back ground information/ Need for Research (150-200 words)

b. Aims and Objectives

4. Study design

4.1Source of Data

4.2 Inclusion and Exclusion criteria of study participants

4.3 Study Groups

4.4 Materials and Methods with Method of Data Collection including sampling size and sampling procedure and method of data analysis. (Explain in detail)

Type of Study (please tick)

Basic Sciences	☐	Clinical	☐	Cross sectional	☐
Retrospective	☐	Epidemiological/Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐	Biological Samples/Data	☐	Systematic Review	☐
Mixed Method	☐	Any other(specify)	☐		

4.5 Outcome Measures

4.6 Applicable only for clinical trials

If there is randomization, how will the participants be allocated to the control and study group(s)?

Describe the method of allocation concealment (blinding / masking), if applicable

5. Assessment of efficacy

5.1 Specification of the efficacy parameters

5.2 Methods and timing for assessing, recording, and analyzing of efficacy parameters

6. Details of Statistical Analysis

Section C – Participant Related Information

7. Recruitment of Research Participants

a. Type of participants in the study

Healthy volunteers ☐ Patients ☐ Vulnerable persons/Special groups ☐

Others (specify) ☐

b. Who will do the recruitment :

c. Participant recruitment methods used :

Posters/leaflets/letters ☐

TV/Radio Ads/Social Media/Institution Website ☐

Patients/Family/Friends visiting hospitals ☐

Telephone ☐

Others ☐

d. Will there be vulnerable persons/special groups involved?

Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons/special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐ Economically and socially disadvantaged ☐

Refugees/Migrants/Homeless ☐ Terminally ill (stigmatized or rare diseases) ☐

Any other (Specify): ☐……

8. Assessment of safety of trial subjects/research participants

8.1 Specification of safety parameters.

8.2 The methods and timing for assessing, recording, and analyzing safety parameters.

8.3 Procedures for eliciting report of and for recording and reporting adverse event

8.4 The type and duration of the follow-up of subjects after adverse events, if any.

8.5 Is there any reimbursement to the participants? Yes / No

If yes, Monetary ☐ Non-monetary ☐ Provide details
……

8.6 Are there any incentives to the participants? Yes / No

If yes, Monetary ☐ Non-monetary ☐ Provide details
……

8.7 Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Yes/No

If yes, Monetary ☐ Non-monetary ☐ Provide details
……

9 Risk and Benefits

9.1 What are the potential risks to the subjects? (Consider social and emotional risks as well as more obvious physical risks)

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐

More than minimal risk or high risk ☐

If Yes, Describe the risk management strategy…….

9.2 What are the potential benefits from the study ?

For the participant ☐

For the society/community ☐

For improvement in science ☐

Please describe how the benefits justify the risks ……

9.3 Are adverse events expected in the study?

Are reporting procedures and management strategies described in the study?
Yes/No

If Yes, Specify …….

9.4 What are the compensations for unexpected risks?

9.5 What are the potential benefits to the participating subjects?

10 Safety and other controls

Does this study involve ionizing radiation, hazardous substances, or hazardous or invasive procedures (including radiological imaging, venepuncture or intimate physical examination)?

YES /NO

If yes, please justify:

11 Informed Consent:

11.1 Waiver of consent

Are you seeking waiver of consent?
If yes, please specify reasons.

11.2 Are you seeking waiver of consent?
If no, answer below

Provide a copy of your consent form and information sheet. Write the procedure about the following:

a. How will consent be obtained from subjects? Will there be a written explanation of the study? How will risks and benefits be explained?

b. Type of consent planned for:

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐

Consent from Legally Authorized Representative (If so, specify from whom) : ☐

Audio-Video (AV) consent ☐

Verbal assent from minor (7-12 yrs) along with parental consent ☐

Other ☐ (specify)
.....

c. Who will obtain the informed consent?
PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐

Other (Specify) …….....……...

d. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐
(Specify)…….....……...

e. Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language	☐	Risks and discomforts	☐
Alternatives to participation	☐	Right to withdraw	☐
Benefits	☐	Purpose and procedure	☐
Data/ Sample sharing	☐	Need to recontact	☐
Confidentiality	☐	Storage of samples	☐
Return of research results	☐	Payment for participation	☐
Compensation for study related injury	☐	Statement that consent is voluntary	☐
Commercialization/ Benefit sharing	☐	Statement that study involves research	☐
Use of photographs/ Identifying data	☐		

Contact information of PI and Member Secretary of EC ☐

Others ☐ (Specify)…….

f. What data will be collected on those who refuse consent?
(Such participants will not be included in the study)

12. Confidentiality

Method of maintaining confidentiality of participants (Explain how the confidentiality will be maintained)

13 **a) Consent of the participant/ subject (copies attached in 3 different languages)**
b) Patient / information sheet (copies attached in 3 different languages)
c) Student undertaking (only in English)
d) Waiver of consent (if applicable)(only in Englsih)

14 **Agreement between collaborating partners**
(if applicable- mention details with documentary evidence))

15. **I agree and undertake to do the following**
To report serious adverse events to the IEC
To report conflict of interest, if any

Principal Investigator: Name and Sign P.G. Guide: Name and Sign

Head of department: Name and Sign Seal of the Department

Collaborator
Designation & Organization (if applicable):

Chairperson, Institutional Ethics Committee: Member Secretary, Institutional Ethics Committee:

Undertaking by the Investigator

01. This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the BVDUDC&H-PUNE-IEC has been obtained.
02. We agree to undertake research proposal involving human subjects and follow the protocol as per the **ethical principles of Declaration of Helsinki. Good Clinical Practice Guidelines and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017**. We will not modify the research protocol, consent, etc. without prior approval by the BVDUDC&H-PUNE-IEC.
03. The investigators agree to obtain a properly informed and understood consent for all research subjects before their inclusion in the study in the informed consent form that is approved by the BVDUDC&H-PUNE-IEC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.
04. The investigators agree to report within a week all serious adverse events (SAE) associated with the study in the SAE form to the BVDUDC&H-PUNE-IEC. In the event of a death of the study subject, the Secretary, BVDUDC&H-PUNE-IEC and SRC, will be informed within 24 hours.
05. **The investigators agree to submit annual progress report of the study in the appropriate form. A final report will be submitted at the end of the study.**
06. Full details on funding and a proposed budget are included with the study proposal. The proposed budget is presented on the specific budget sheet
07. We understand that the BVDUDC&H-PUNE-IEC is concerned about transparent financial transactions during the study. A report on how the study funds were utilized will be presented to the EC along with the final project report at the end of the study.(**In case of sponsored study**)
08. For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the study. The investigators will also ensure that in the event of complications arising directly due to the study or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.
09. The investigators state that they do not stand to gain financially from the commercial sponsor and don't have conflict of interest in the drug or product by way of consultations, shareholding, etc.
10. The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the BVDUDC&H-PUNE-IEC, approved protocol.
11. All data collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of BVDUDC&H-PUNE.
12. The salaries to staff employed for the research project will be as shown in the budget sheet and in accordance with the provisions made by the funding agencies. .(**In case of sponsored study**)
13. The case records (source documents) will be made available to members of the SRC or BVDUDC&H-PUNE-IEC any time for random verification and monitoring. The case records (source documents) will be preserved in the premises of BVDUDC&H-PUNE for at least 5 years after the last approval of application or publication.

14. The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.
15. All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of BVDUDC&H-PUNE before they are released or presented elsewhere. The investigators will submit a copy of the abstract to the SRC and BVDUDC&H-PUNE-IEC well in advance of any proposed presentation at national or international conferences or seminars.
16. The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the BVDUDC&H-PUNE staff or published in a peer-reviewed journal.
17. All serious injuries arising from the study will be the responsibility of the investigators. The investigators agree to ensure that the sponsors undertake a product liability insurance to cover any expenses for injury or compensation arising from the study treatment.
18. The investigators agree to transfer 15% of the total budget to BVDUDC&H-PUNE as service charges. This will not apply to intramural projects, those co-sponsored by BVDU Dental College & Hospital Pune and collaborative projects with BVDUDC&H-PUNE
19. The investigators agree that the grant money will be spent in accordance with the budget proposal only. The funds will not be used for any other purposes without prior approval from the BVDUDC&H-PUNE-IEC. Thirty percent of the surplus grant if left over at the end of the study will be credited to BVDUDC&H-PUNE The remaining 70% of the surplus grant money may be used by the investigators for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc after obtaining permission from the BVDUDC&H-PUNE-IEC. In case of government grants, the unspent balance will be spent/ returned as per the directives given along with the project sanction letter.
20. The investigators will constantly inform the BVDUDC&H-PUNE-IEC about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other study documents, etc. as and when they occur. No major changes in the treatment arms or the study protocol or randomization technique will be carried out without prior permission of the BVDUDC&H-PUNE-IEC.
21. The investigators will comply with all policies and guidelines of the BVDUDC&H-PUNE and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.

We the investigators of the proposed study have read all the statements listed above and agree to observe / undertake these BVDUDC&H-PUNE-IEC requirements while conducting our proposed project / study.

Sign of PI:

Sign of Co-I / P.G. Guide:

Head of Department:

Date:

Department/ Institution Seal:

CHECKLIST: (Ensure print out of entire checklist is on single separate page)

All the researchers are requested to kindly fill the checklist before submitting the proposal to the IEC.

Sr. No.	Items	Yes	No	NA	Enclosure No	EC Remarks (if applicable)
A	ADMINISTRATIVE CHECKLIST					
1	Covering Letter					
2	Good Clinical Practice (GCP) training of investigators in last three years.					
3	Approval of Institutional Research Board					
4	Agreement between collaborating partners (if the study/ investigations are going to be performed at any other lab/Institution e.g. Praj Lab/Bharati Hospital/IRSHA)					
5	Copy of contract or agreement or sponsor letter (for sponsored studies)					
6	Undertaking of Expenses (for non-sponsored or self-sponsored studies)					
B	PROPOSAL RELATED CHECKLIST					
1	Completely filled copy of Initial Review Form					
2	Waiver of consent (if applicable)					
3	Participant Informed Consent (English, Hindi, Marathi)					
4	Participant Information Sheet (English, Hindi, Marathi)					
5	Assent form (12-18 age group) (English, Hindi, Marathi)					
6	Case Proforma/Questionnaire/Case Report forms as applicable					
7	Registration with CTRI if applicable.					
C	ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY					
1						

Name and Signature of Primary Investigator Name and Signature of the Guide

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(REVIEWER'S COMMENTS)

EC No……(For office use only)

Format of Reviewers Comment (IEC Member) **Date:**

Tittle of the project: _____

_____

Name of the student/ P.I: _____

Name of the department: _____

Sr No		**Approved**	**Not Approved**	**Suggestions**
1	Overview of research/ Background			
2	Aims and objectives			
3	Study design/ Methodology			
4	Recruitment procedures of research participant			
5	Assessment of Efficacy			
6	Statistical Analysis			
7	Assessment of safety of research participants			
8	Expected risks and benefits to research participants mentioned			
9	Compensation offered in case of risk			
10	**Drug study specific requirements**			
11	Procedures for informed consent form/ and patient information sheet.			
12	Ensuring Confidentiality			

Any other comments of the Reviewer:

Name and Signature of the IEC member: