



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



**Bharati Vidyapeeth Deemed University  
Dental College & Hospital, Pune  
Institutional Ethics Committee  
June 2017 to May 2019**



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

**Institutional Ethics Committee Report  
June 2017-May 2019**

**Registration no – ECR/328/Inst/MH/2013/RR-16**



**Bharati Vidyapeeth Deemed to be University**  
**Dental College and Hospital, Pune**  
**Institutional Ethics Committee**

The Institutional Ethics Committee (IEC) oversees the ethical conduct of the research which is undertaken by the researchers. It encourages all the students and staff members to carry out research and promotes the ethical use of the participants involved in research in accordance with the ethical norms for the welfare of the study subjects.

This report presents an overview of the functions and activities of the Institutional Ethics Committee for a period from June 2017 to May 2019.

The Institutional Ethics Committee of Bharati Vidyapeeth Deemed to be University was first registered in 2013 with the Drug Controller General of India (DCGI), New Delhi from 05.06.2013 to 05.06.2016 and then re-registered for a period from 06.06.2016 to 05.06.2019. (Reg no – ECR/328/Inst/MH/2013/RR-16)

All the members of the Institutional Ethics Committee are certified by the Ethical Research Initiatives and are trained for ICH, Good Clinical Practices (GCP) and Schedule Y.

Research Ethics is specifically interested in the analysis of ethical issues that are raised when human beings are involved as participants in Research Ethics.

**Objectives of the Institutional Ethics Committee -**

1. To protect human participants during the study.
2. To ensure that research is conducted in a way that serves interest of individuals, groups and/or society.
3. To examine specific research activities and projects for their ethical soundness, analyzing issues such as management of risk, adverse effects, protection of confidentiality and the process of informed consent.

It is the endeavor of the institute to maintain high ethical standards and justice for all.

### **Composition of the Institutional Ethics Committee**

The Institutional Ethics Committee has 12 members – 07 external members and 05 internal members.

1. Dr Ramandeep Dugal, Chairperson, MDS (Prosthodontics), Principal- M.A. Rangoonwala College of Dental Sciences and Research Centre, Pune
2. Dr Revati Deshmukh, Member Secretary, MDS Professor & Head (Oral and Maxillofacial Pathology & Microbiology)- B V D U D C&H, Pune
3. Adv Sarita Dugane, Legal expert, B.Com, LLB, New Law College, BVDU, Pune
4. Dr Arul mozhi S, Subject expert (Pharmacology), M.Pharm, PhD, BVDU Poona College of Pharmacy- Pune
5. Mrs. Asavari Joshi, Social Scientist, MD (Biotechnology), Interactive Research School for Health Affairs, Pune
6. Dr Usha Verghese, Social worker, PhD (Social work), MSW College, BVDU, Pune
7. Dr Supriya Bhalerao, Subject expert, MD (Ayurved), Interactive Research School for Health Affairs, Pune
8. Dr Vanita Patwardhan, Lay person, PhD (Psychology), Professor, Jnana Prabodhini, Samshodhan Sanstha- Pune
9. Dr Amita Mali, Subject expert (Periodontology), MDS, BVDU DC&H, Pune
10. Dr U.B.Gajare, Subject expert (Prosthodontics), MDS, BVDU DC&H, Pune
11. Dr Shubhangi Wadgaonkar, Subject expert (Microbiology), BVDU DC&H, Pune
12. Dr Mhapuskar Amit, Subject expert (Oral Medicine and Radiology), BVDU DC&H, Pune

Co-ordinator – Dr Priya Deo, Asst Professor, Oral Pathology and Microbiology, BVDUDC&H, Pune

Due to retirement/resignation of few members of the committee, some new members were appointed as follows:

1. Dr Arul mozhi S replaced Dr Bodhankar as a subject expert, Pharmacology from 20-09 2017
2. Dr U.B.Gajare replaced Dr S.V.Bhide as a subject expert, Prosthodontics from 20-09-2017
3. Dr Vanita Patwardhan replaced Ms Archis SV as a Lay person from 28-03-2018

**Bharati Vidyapeeth Deemed to be University**

**Dental College and Hospital, Pune**

**Institutional Ethics Committee  
Academic year 2017-2018**

The Institutional Ethics Committee, Bharati Vidyapeeth Deemed to be University Dental College and Hospital conducted 5 meetings in this academic year.

All meetings of the Institutional Ethics Committee were scheduled and conducted after the meetings of the Institutional Research Committee for reviewing of the proposals which required ethical clearance.

The Committee had around 9-12 members as quorum for nearly all the meetings.

A Mock Ethics Committee meeting was also conducted to make the students familiar with the process.

Every submission was reviewed by the members of the Institutional Ethics Committee and students were asked to make the suggested changes for ethical approval. The ethics approval letter was issued to the researcher after submission of the modified copy with the suggested changes.

Minutes of each meeting are recorded by the Institutional Ethics Committee BVDUDCH, Pune.

The number of research proposals which were reviewed and approved by the Institutional Ethics Committee during the academic year 2017-2018 and are as follows:

<b>Sr no</b>	<b>Type of Proposal</b>	<b>Number of Proposals</b>	<b>Status</b>
1	Postgraduate Dissertations	26	Approved
2	PhD Research Proposal	01	Approved
3	Short studies by Faculty, PG students, Interns and UG students	24	Approved

#### **Summary of each meeting**

<b>Sr no</b>	<b>Date</b>	<b>Number of projects reviewed</b>	<b>Number of projects approved</b>
1	12 <sup>th</sup> September 2017	06	05
2	15 <sup>th</sup> December 2017 22 <sup>nd</sup> December 2017 27 <sup>th</sup> December 2017	36	36
3	March 2018	10	10

**Institutional Ethics Committee meeting**  
**12<sup>th</sup> September 2017**  
**Post-Graduate dissertations**

<b>Sr.no.</b>	<b>Name of the Post-Graduate student</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Dr Wasim Bhashir Pathan	Dr Kiran Gadre	Oral and Maxillofacial Surgery	Microbial colonization of antiseptic impregnated suture material versus conventional suture material in minor oral surgery – A prospective comparative clinical study
2	Dr. Sanjana Sethi	Dr. Amod Patankar	Oral and Maxillofacial Surgery	Comparative evaluation of socket preservation with and without autogenous dentin graft in bilateral mandibular third molar extraction
3	Dr. Anusha Shankar	Dr. Veera Bhonsale	Orthodontics and Dentofacial Orthopaedics	Comparative evaluation of the surface morphology of metal brackets slot before and after their use in the oral cavity using scanning electron microscope (SEM)

**Short studies (Interns/ Undergraduate students)**

<b>Sr.no.</b>	<b>Name of the Intern/Undergraduate student</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Drupal Shah Suman Choudhary	Dr Amol Kamble	Pedodontics and Preventive Dentistry	Intra-oral assessment of children with acute lymphoblastic leukemia undergoing chemotherapy: An observational study
2	Dr. Harshit Bhadani	Dr. Surekha Chavan	Oral Pathology and Microbiology	Role of Candida in different grades of leukoplakia

Total number of Post-graduate Dissertations approved

03

Total number of short studies approved

02

**Total number of projects approved**

**05**

**Institutional Ethics Committee meeting**  
**15<sup>th</sup>, 22<sup>nd</sup> and 27<sup>th</sup> December 2017**

**PhD thesis**

<b>Sr no</b>	<b>Name of the PhD student</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Dr Swapna Patankar	Dr Revati Deshmukh	Oral Pathology and Microbiology	Evaluation of Hepatitis B & Hepatitis C Co-infections from blood samples of HIV sero-positive patients on Highly Active Anti-Retroviral Therapy & their co-relation to the oral manifestations - A Clinical & Microbiological Study

**Post-graduate Dissertations**

<b>Sr. no.</b>	<b>Name of the Post-graduate student and Year of admission</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Dr Bhatia Shivani Anil	Dr Anupam Sharma	Conservative Dentistry	Comparative evaluation of various storage media on fracture resistance of reattached crown fragment- An in vitro study
2	Dr. Bansod Sonali Jagannath 2017	Dr. Ashwini Gaikwad	Conservative Dentistry	Comparative Evaluation of Push-Out Bond Strength and failure modes of Fiber Post cemented with different Adhesive Resin Cements- An in-vitro study.
3	Dr. Esha Sunil Kedia 2017	Dr. Jyoti Mandlik	Conservative Dentistry	Effect of addition of an anti-oxidant in calcium hydroxide and chlorhexidine, when used in combination as an intra-canal medicament on fracture resistance of root dentin, at two different time intervals: an in-vitro study.
4	Dr. Sharma Anirudha Girish 2017	Dr. Varsha Pandit	Conservative Dentistry	Comparative evaluation of effect of 17% Ethylenediaminetetraacetic acid (17% EDTA) and Chitosan on fracture resistance of endodontically treated teeth: An in vitro study.



5	Dr. Shah Krishna Ketan 2017	Dr. Aniket Jadhav	Conservative Dentistry	Comparative evaluation of fracture resistance of endodontically treated teeth restored with nanohybrid composite, dual cure core build-up material and short fiber reinforced composite: An in-vitro study.
6	Dr. Naik Bhakti Vidhyadhar 2017	Dr. Vijaysinh More	Prosthodontics	Comparative evaluation of four different materials for peripheral seal, using single step border moulding technique in maxillary edentulous arches – An In-vivo Study
7	Dr. Firdous Ahmad Najar 2017	Dr. Shailesh Deshmukh	Orthodontics	Determination of suitable sites for orthodontic mini-screw insertion on the mandibular buccal shelf area: A cone-beam computed tomography study.
8	Dr. Rampurawala Abdulqadir Mulla Husain 2017	Dr. Amol Patil	Orthodontics	Evaluation of the effect of ultraviolet photofunctionalization on peri-implant osteogenesis in titanium orthodontic miniscrews: a split-mouth study.
9	Dr. Jagtap Sneha Baburao 2017	Dr. Veera Bhosale	Orthodontics	Comparative evaluation of interrupted and intermittent forces on canine retraction: An in vivo study.
10	Dr. Dhok Anvita Pravin 2017	Dr. Gauri Vichare	Orthodontics	Assessment of pulp tooth ratio of maxillary canine and the status of mid-palatal suture maturation- A cone beam computed tomography study.
11	Dr. Sarah Mariam 2017	Dr. Amita Mali	Periodontology	Comparative assessment of periodontal status in subjects with and without Polycystic Ovary Syndrome and its correlation with Body Mass Index.
12	Dr. Princy Thomas 2017	Dr. Pramod Waghmare	Periodontology	Comparative evaluation of metronidazole and chlorhexidine gluconate gel with metronidazole gel alone as a local drug delivery system in patients with chronic periodontitis as an adjunct to scaling and root planning- A clinical and microbiological study.
13	Dr. Shilpa Mule Manoharrao	Dr. Vishakha Patil	Periodontology	Comparative evaluation of toxic effects of two herbal extracts (2%

	2017			neem and 2% tulsii) with 0.2% chlorhexidine gluconate on oral cell line.
14	Dr. Jashneet Dhupar 2017	Dr. Alok Patel	Pedodontics and Preventive Dentistry	A comparative evaluation of cytokines as inflammatory markers in the saliva of Down's Syndrome patients before and after oral prophylaxis.
15	Dr. Mutha Komal Sanjay 2017	Dr. Preetam Shah	Pedodontics and Preventive Dentistry	Comparative evaluation of the effectiveness of irrigation with 5.25% sodium hypochlorite with and without ultrasonic activation in the root canal system of primary molars: An in-vitro study.
16	Dr. Manasi Rajendra Shimpi 2017	Dr. Shweta Chaudhary	Pedodontics and Preventive Dentistry	Assessment of the Efficacy of Thermography for the Detection of Demineralisation and Early Carious Lesions - an In-Vitro Study.
17	Dr. Shraddha Ashok Kadam 2017	Dr. Sanket Kunte	Pedodontics and Preventive Dentistry	Comparison of Penetration Depth, Microleakage and Surface Roughness of a Newer Infiltrant Resin Material and Flowable Nano Composite : an In Vitro Study.
18	Dr. Abhyankar Purva 2017	Dr Revati Deshmukh	Oral Pathology and Microbiology	Comparative analysis of Feulgen and Papanicolaou stains for determination of Barr body using cytosmeears- a forensic study.
19	Dr. Priyadarshini Banerjee 2017	Dr. Rajesh Kshirsagar	Oral and Maxillofacial Surgery	Comparative Evaluation Of Virtually Planned Implant Placement With Implants Placed Using Computer Aided Surgical Templates.
20	Dr. Pallavi Sanjeevkumar Rathi 2017	Dr. .Kiran Gadre	Oral and Maxillofacial Surgery	Comparative study to evaluate the effect of intramassetric dexamethasone with methylprednisolone on postoperative sequelae after mandibular third molar surgery.
21	Dr. Tadas Kisana Dhanraj 2017	Dr. Rajshekhar Halli	Oral and Maxillofacial Surgery	Comparative evaluation of One Point Fixation at Zygomaticomaxillary buttress Area With Two Point Fixation at Zygomaticomaxillary buttress And Frontozygomatic suture Areas In Management Of Zygomaticomaxillary complex fractures.

22	Dr. Limbhore Mayur Vilas 2017	Dr.Shandilya Ramanojam.	Oral and Maxillofacial Surgery	Comparative evaluation of changes in blood glucose level, blood pressure and pulse rate using plain lignocaine and lignocaine with adrenaline (1:1,00,000) in diabetic (type II) patients undergoing routine dental extractions.
23	Dr. Sharma Reshmi Ramji 2017	Dr Amod Patankar	Oral and Maxillofacial Surgery	Comparative evaluation of soft tissue parameter on immediately placed and loaded implants in esthetic zone following socket shield technique with the contralateral healthy natural counterpart.

**Short Studies by Faculty, Post-graduate students, Interns and Undergraduate students**

Sr. no.	Name of the Principal Investigator	Name of the Guide/Co-Investigator	Name of the Department	Title
1	Dr. Praveena Kulkarni	Dr. Moghe	Oral Pathology and Microbiology	Comparative evaluation of anticancer property of Mentha arvensis mediated silver nanoparticles with doxorubicin on human oral squamous cell carcinoma cell lines.
2	Ms. Alpa Newaskar & Ms. Neha Pradhan	Dr. V.V.Kulkarni	Oral Pathology and Microbiology	Dermatoglyphics in subjects with potentially malignant oral lesions and conditions – an observational study.
3	Ms. Vaishnavi Borse	Dr. V.V. Kulkarni	Oral Pathology and Microbiology	Effect of Application of Turmeric on the Surface of Enamel – An Observational Study.
4	Manali Bhansali	Dr. Praveena.V. Kulkarni	Oral Pathology and Microbiology	A comparison of methylene blue-acid fuchsin and alizarin red S stain for differentiating calcification and cementum-like material in oral lesions.
5	Ankita Kharose	Dr.Praveena.V. Kulkarni	Oral Pathology and Microbiology	Comparative evaluation of colour change and enamel surface texture change on extracted teeth following application of strawberry and banana peel.
6	Mr. Pratik Maity & Ms. Khabiya Prerana	Dr. Rajshekhar Halli	Oral and Maxillofacial Surgery	Efficacy of Turmeric And Tulsi in Management of Oral Submucous Fibrosis: A Clinical Observational Study.
7	Dr. Nikita Kadam	Dr. Sanket Kunte	Pedodontics and Preventive Dentistry	Comparative evaluation of the effect of Pomegranate Peel extract and Chlorhexidine 0.2% mouthwash on salivary pH in Children between 6-8 years of age: An in vivo study.
8	Dr. Smruti Venkatraman	Dr. Rahul Lodaya	Pedodontics and Preventive Dentistry	Assessment of knowledge and attitude about oral health care among parents of children with cerebral palsy.
9	Dr. Dhanashree Dalal	Dr. Alok Patel	Pedodontics and Preventive Dentistry	Identification and assessment of factors predicting behavior of the child during first dental visit.

10	Dr. Nikita Nishan	Dr. Preetam Shah	Pedodontics and Preventive Dentistry	Assessment of awareness and knowledge among school children and sports coaches engaged in contact sports regarding the use of mouthguard for prevention of dental trauma.
11	Dr. Suman R. Gupta	Dr Rajesh Kshirsagar	Oral and Maxillofacial Surgery	Photographic analysis of Soft Tissue Changes and Cephalometric Analysis of skeletal changes following superior repositioning of maxilla using Le Fort I osteotomy.
12	Ms. Shubhita Sethi & Ms. Dhvani Vasa	Dr. Siddharth Shinde	Orthodontics	Evaluation of tongue position from rest to centric occlusion in the subjects of skeletal class II division 1 malocclusion, skeletal class II division 2 malocclusion and class 1 normal occlusion— a cephalometric comparative study.

Total number of PhD thesis approved	01
Total number of PG Dissertations approved	23
Total number of short studies approved	12
<b>Total number of projects approved</b>	<b>36</b>

**Institutional Ethics Committee meeting**  
**March 2018**  
**Short studies by Faculty and Post-graduate students**

<b>Sr no</b>	<b>Name of the Principal Investigator</b>	<b>Name of the Co-Investigator</b>	<b>Department</b>	<b>Title</b>
1	Dr Revati Deshmukh	Dr Priya Nimish Deo	Oral Pathology and Microbiology	A comparative analysis of matrix metalloproteinase -9(MMP-9) for assessment of aggressiveness in different histological variants of Ameloblastoma
2	Dr Jashneet Dhupar	Dr Alok Patel	Pedodontics and Preventive Dentistry	Comparative evaluation of adhesive bond strength and sustained fluoride release of a chitosan infused resin modified glass ionomer cement with resin modified glass ionomer cement – An invitro study
3	Dr Raheja Soniya	Dr Rahul Lodaya	Pedodontics and Preventive Dentistry	Evaluation of parental awareness about association of premature loss of primary maxillary anterior teeth and speech changes in preschool children: A survey study
4	Dr Manasi Shimpi Study 1	Dr Shweta Chaudhary	Pedodontics and Preventive Dentistry	Comparative evaluation of salivary changes and oral indices in Paediatric patients having chronic renal disease and juvenile diabetes with healthy controls
5	Dr Manasi Shimpi Study 2	Dr Shweta Chaudhary	Pedodontics and Preventive Dentistry	Assessment of thermal changes using thermography for the detection of artificially induced fractures in teeth – an in vitro study
6	Dr Shraddha Kadam	Dr Sanket Kunte	Pedodontics and Preventive Dentistry	Comparison of Efficacy of Jet Injector with Topical Anesthetic gel before palatal infiltration anaesthesia in children of age 6 to 12 years: An in vivo study
7	Dr Heena Kagdi	Dr Shweta Chaudhary	Pedodontics and Preventive Dentistry	Comparative Finite element stress analysis of Nusmile and Kids-e-Zirconia crowns
8	Dr Purva Abhyankar		Oral Pathology and Microbiology	Assessment and comparison of the plasma vitamin B12 levels in patients with oral potentially malignant and malignant lesions

9	Dr Amit Mhapuskar	Dr Priya Agarwal	Oral Medicine and Radiology	Comparative evaluation of salivary levels of tumor necrosis factor-alpha in oral submucous fibrosis and healthy individuals
10	Dr Priya Deo Dr Rashmi Sane	Purva Sachin Doshi	Oral Pathology and Microbiology	Comparative estimation of dental age by using Demirjian's and Nolla's method in residents of Pune city

**Total number of short studies approved**

**10**

All meetings were conducted amicably and in a disciplined manner.

We thank all the ethics committee members and the Principal, BVDUDCH-Pune, for their support in conducting these meetings smoothly.

**Dr Revati Deshmukh**  
**Member Secretary**  
**Institutional Ethics Committee**

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

**Institutional Ethics Committee  
Academic year 2018-2019**

The Institutional Ethics Committee, Bharati Vidyapeeth Deemed to be University Dental College and Hospital conducted 7 meetings in the academic year 2018-2019 for reviewing of research proposals which required ethical clearance

Every submission was reviewed by the members of the Institutional Ethics Committee and researchers were asked to make the suggested changes for ethical approval.

The Committee had around 9-12 members as quora for nearly all the meetings. Minutes of each meeting are recorded by the Ethics Committee section of BVDUDCH, Pune.

The following research proposals were reviewed and approved by the Institutional Ethics Committee

<b>Sr no</b>	<b>Type of Proposal</b>	<b>Number of Proposals</b>	<b>Status</b>
1	Postgraduate Dissertations	31	Approved
2	PhD Research Proposals	02	Approved
3	Short studies by Faculty, PG students, Interns and UG students	41	Approved



### Summary of the meetings

<b>Sr no</b>	<b>Date</b>	<b>Number of projects reviewed</b>	<b>Number of projects approved</b>
1	14 <sup>th</sup> September 2018	12	12
2	12 <sup>th</sup> December 2018	32	32
3	9 <sup>th</sup> January 2019	32	32
4	1 <sup>st</sup> February 2019		
5	19 <sup>th</sup> March 2019	13	13
6	5 <sup>th</sup> April 2019	10	10
7	8 <sup>th</sup> May 2019	07	07

Two PG dissertations from the Department of Pedodontics and Preventive Dentistry will be given Ethical approval letter after submission of the drug safety data sheet by the Researcher.

## Institutional Ethics Committee meeting

**14<sup>th</sup> September 2018**

### Short studies

Sr no	Name	Department	Project title
1	Dr. Amit Mhapuskar, Principal Investigator  Dr Richa Jain Co-Investigator	Oral Medicine and Radiology	Efficacy of Ultrasound Massage Therapy in Myofascial Pain – A randomized single blind clinical study
2	Dr. Amit Mhapuskar – Principal Investigator  Miss Mekhala Ratnaparkhi, Miss Pranjali Pokharkar – Co-Investigators	Oral Medicine and Radiology	Co-relation between presence of ponticulus posticus on the lateral cephalogram and headache. A prospective single-blinded study
3	Dr. Shameeka Thopte, Principal Investigator  Dr. Shams Ul Nisa, Co-Investigator	Oral Medicine and Radiology	Comparative Evaluation between modified Kvaal's formula and Coronal pulp cavity index for dental age estimation – A radiographic study
4	Dr. Jashneet Dhupar, Principal Investigator  Dr Alok Patel Co-Investigator	Pedodontics and Preventive Dentistry	Change in the attitude towards oral and dental health care, among children of 6-8 years after undergoing invasive dental treatment
5	Dr. Komal Sanjay Mutha Principal Investigator  Preetam Shah, Co-Investigator	Pedodontics and Preventive Dentistry	Current Trends And Approach Of General Dentists Regarding Pediatric Dental Care in their Private Practices: A Survey
6	Dr Sanket Kunte Principal Investigator	Pedodontics and Preventive Dentistry	Comparative Evaluation of Antimicrobial efficacy of Pistacia Integerrima aqueous extract, Quercus infectoria aqueous extract and 2% chlorhexidine as root canal irrigants against Streptococcus Mutans and E-Faecalis
7	Dr. Rajesh Kshirsagar Principal Investigator  Ms Manhar kaur shinh Co-Investigator	Oral and Maxillofacial Surgery	Curriculum of the first year of dental school – Perception and Challenges
8	Dr. Prakhhar Kapoor – Principal Investigator, Reader – Sinhgad Dental College	Oral Pathology and Microbiology, Sinhgad Dental College and Hospital, Pune	Assessment of prospects amongst the interns and clinical perspective amongst general dental practitioners about oral pathology – a cross sectional questionnaire based study

	Dr Priya Nimish Deo – Co-Investigator, Asst Professor,BVDUDCH		
9	Dr. Siddharth Shinde – Principal Investigator  Ms Shravani Parandekar and Ms Riyaa Ranade Co-Investigators	Orthodontics and Dentofacial Orthopaedics	Comparison of YEN Angle, W Angle and conventional parameters(ANB angle, BETA angle and Wits appraisal) in assessment of skeletal jaw base discrepancy
10	Dr. Venkatesh Kulkarni Principal Investigator  Ms Riyaa Ranade Ms Shravani Parandekar Co-Investigators	Oral Pathology and Microbiology	Evaluation of serum lactate dehydrogenase levels in tobacco consumers: An observational study
11	Dr. Venkatesh Kulkarni – Principal Investigator  Ms Shravani Parandekar Ms Riyaa Ranade Co-Investigators	Oral Pathology and Microbiology	Evaluation of protein activity in different grades of oral dysplasia using Phosphotungstic acid – haematoxylin stain (PTAH stain)
12	Dr. Praveena Kulkarni – Principal Investigator  Ms Gayatri Dehingia Ms Unnati Mehta Co-Investigators	Oral Pathology and Microbiology	Evaluation of Dental anxiety and phobia in adult dental patients : A descriptive study

**Total number of projects approved – 12**

### Institutional Ethics Committee meetings

**12<sup>th</sup> December 2018, 9<sup>th</sup> January 2019, 1<sup>st</sup> February 2019**

#### PhD thesis

<b>Sr. no.</b>	<b>Name of the PhD student</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Dr Venkatesh Kulkarni	Dr Revati Deshmukh	Oral Pathology and Microbiology	Comparative analysis of Eosinophil Cationic Protein in Saliva, Serum and Tissue of Normal, Oral Potentially Malignant Disorders and Oral Squamous Cell Carcinoma

#### Post-graduate Dissertations

<b>Sr. no.</b>	<b>Name of the Post-graduate student and Year of admission</b>	<b>Name of the Guide</b>	<b>Name of the Department</b>	<b>Title</b>
1	Dr Sardar Siddhi Sunil 2018	Dr Ajay V. Sabane	Prosthodontics and Crown and Bridge	Comparative Evaluation of the Bond Strength of CAD/CAM Monolithic Zirconia Copings using Three Luting Agents and Two Different Finish Lines: An In-Vitro Study
2	Dr Devyani Mahesh Shinde 2018	Dr Rajashree Jadhav	Prosthodontics and Crown and Bridge	Comparative evaluation of effect of Desensitizing agent on retention of CAD/CAM Metal Copings and CAD/CAM Zirconia Copings cemented with a commercially available luting cement – An In-Vitro Study
3	Dr Revdekar Anisha Hemant 2018	Dr Anand Sabane	Orthodontics and Dentofacial Orthopaedics	Comparison of the effects of laser irradiation and conventional acid etching on the surface characteristics and bond strength of bonded molar tubes- An in-vitro study
4	Dr Vichare Sharvari Shekhar 2018	Dr Shailesh Deshmukh	Orthodontics and Dentofacial Orthopaedics	Evaluation of stress distribution and displacement patterns in maxillary expansion by light continuous force – A Finite Element Model Study
5	Dr Satra Priyanka Pinakin 2018	Dr Gauri Vichare	Orthodontics and Dentofacial Orthopaedics	Assessment of maxillary and mandibular base length, arch length and dental crowding in different jaw rotations

6	Dr Dhanashree Khot  2018	Dr Veera Bhosale	Orthodontics and Dentofacial Orthopedics	Comparison of Matrix Metalloproteinase-8 levels in peri mini-screw crevicular fluid after immediate and delayed orthodontic loading – An In-Vivo study
7	Dr Prashant Kumar  2018	Dr Amol Patil	Orthodontics and Dentofacial Orthopedics	Comparative evaluation of the effect of micro-osteoperforations on the rate of orthodontic tooth movement
8	Dr Gholap Chaitanya Rajesh  2018	Dr Sanket Kunte	Pedodontics and Preventive Dentistry	Comparison of Microleakage and Cariostatic Properties of Two Commercially Available Pit and Fissure Sealants – An in vitro study
9	Dr Kade Kimaya Kiran  2018	Dr Shweta Chaudhary	Pedodontics and Preventive Dentistry	Comparative evaluation of the remineralization potential of fluoride containing toothpaste, honey-ginger paste and ozone. An in-vitro study
10	Dr Kenjale Manasi Anand  2018	Dr Preetam Shah	Pedodontics and Preventive Dentistry	Clinical Evaluation Of Overall Efficacy And Pain Perception Of Ultrasonic Oscillating Tips and Conventional High Speed Burs For removal of Dental Caries In Children In the Age Group of 6-8 Years
11	Dr Shah Swarali Bharat  2018	Dr Chetan Bhat	Pedodontics and Preventive Dentistry	Efficacy of two different mouth rinses in inhibiting the growth of Streptococcus mutans on toothbrush bristles
12	Dr Bhalerao Aishwarya Bhalchandra  2018	Dr Amita Mali	Periodontology	Comparative evaluation of dentinal tubule diameter and patency by using Calcium sodium phosphosilicate and pro arginine containing dentifrice – An In-vitro ESEM study
13	Dr Shendge Pooja Avinash  2018	Dr Nilima Landge	Periodontology	Assessment of serum Ceruloplasmin levels in individuals with gingivitis and periodontitis before and after scaling and root planing
14	Dr Bhole Shweta Sunil  2018	Dr Vishakha Patil	Periodontology	Assessment of antiviral effect of Azadirachta Indica(neem) mouthwash along with scaling and root 19lanning against herpes simplex and cytomegalovirus in individuals with gingivitis and chronic periodontitis

15	Dr Nitin Kumar Dongre  2018	Dr Prakash Vhatkar	Periodontology	Comparative evaluation of efficacy of aloe vera mouthwash and chlorhexidine gluconate mouthwash as an adjunct to scaling and polishing in chronic gingivitis cases – An In-Vivo study
16	Dr Thombare Shashwat Ram  2018	Dr Amit Chaudhari	Periodontology	Comparative evaluation of preoperative thickness of keratinized soft tissue with the changes in the level of hard tissue in relation to implant platform within 6 months after the implant placement
17	Dr Vivek Singh Tanwar  2018	Dr Pramod Waghmare	Periodontology	Comparative evaluation of Diode Laser and 1% Chlorhexidine gel as Local drug delivery along with scaling and root planing in the treatment of Chronic Periodontitis – An In Vivo Study
18	Dr Virendra Sinhasane  2016	Dr Revati Deshmukh	Oral Pathology and Microbiology	Comparative evaluation of oral potentially malignant disorders using wooden spatula and cytobrush – An In vivo study
19	Dr Gandhe Pooja Subhash  2018	Dr Ashwini Gaikwad	Conservative Dentistry and Endodontics	Comparative evaluation of pushout bond strength of biobond after root dentin conditioning with different irrigating solutions – An invitro study
20	Dr Gujarathi Nirmitee Narendra  2018	Dr Jyoti Mandlik	Conservative Dentistry and Endodontics	Evaluation of apical leakage after immediate and delayed post space preparation using different root canal sealers: An in-vitro study
21	Dr Dev Nidhi Sunil  2018	Dr Anupam Sharma	Conservative Dentistry and Endodontics	Comparative evaluation of microtensile bond strength of composite resin to dentin after pretreatment with two different matrix metalloproteinase inhibitors: An in-vitro study
22	Dr Sengupta Anandita Devprasad  2018	Dr Varsha Pandit	Conservative Dentistry and Endodontics	Comparative study of the influence of instrument tapers on the fracture resistance of endodontically treated teeth using hand and rotary files

23	Dr Shweta 2018	Dr Sarita Singh	Conservative Dentistry and Endodontics	Comparative evaluation of push out bond strength of two endodontic sealers to root dentin : An In-vitro study
24	Dr Deshpande Sushmita Sudarshan 2018	Dr Aniket Jadhav	Conservative Dentistry and Endodontics	Comparative evaluation of three pre-cleaning protocols in the elimination of biologic debris on rotary nickel titanium endodontic instruments prior to sterilization – An In-vitro study
25	Dr Richa Jain 2018	Dr Amit Mhapuskar	Oral Medicine and Radiology	Comparison of Efficacy of Combination Therapy (Low Level Laser Therapy (LLLT) and Topical Steroids) with Topical Steroid Therapy only in patients with Symptomatic Oral Lichen Planus – In Vivo Study
26	Dr Krishnanunni Nair 2018	Dr Amod Patankar	Oral and Maxillofacial Surgery	Evaluation of Changes in Alveolar Width and Crestal Osseous Changes Around Dental Implants Placed Using Osseodensification Drilling Combined with Segmental Ridge Split Technique and Simultaneous Implant Placement in Narrow Alveolar Ridges: A Clinical and Radiographic Study
27	Dr Shubham Dilip Katariya 2018	Dr Rajshekhar Halli	Oral and Maxillofacial Surgery	Comparative evaluation of post-operative sequelae using diode laser and conventional scalpel blade for soft tissue incision in impacted mandibular third molar surgery – A prospective split mouth study
28	Dr Prasamita Mishra 2018	Dr Rajesh Kshirsagar	Oral and Maxillofacial Surgery	Evaluation of primary and secondary stability, and crestal osseous changes in short implants – A clinico radiographic study
29	Dr Rakhi Syam Purkayastha 2018	Dr Samir Joshi	Oral and Maxillofacial Surgery	Comparison of efficacy for 2% lidocaine with adrenaline (1:2,00,000) and 4% articaine with adrenaline (1:1,00,000) in inferior alveolar nerve block

**Total number of projects approved**

**29**

## **Institutional Ethics Committee meeting**

**19<sup>th</sup> March 2019**

### **PhD thesis**

<b>Sr no</b>	<b>Name</b>	<b>Department</b>	<b>Title</b>
1	Dr Priya Deo	Oral and Maxillofacial Pathology and Oral Microbiology	Profiling of the Oral Microbiome of Normal, Oral Potentially Malignant Disorders and Oral Squamous Cell Carcinoma

### **Short studies**

<b>Sr no</b>	<b>Name</b>	<b>Department</b>	<b>Title</b>
<b>1</b>	Dr. Manjula Hebbale Dr. Darshan Hiremutt Dr. Rashmi Sane Dr. Rajshekar Halli	Oral Medicine and Radiology	Management of Homogenous Oral Leukoplakia by Diode Laser and Conventional Blade: A comparative study
<b>2</b>	Dr. Meenal Tepan Mrs. Anjali Naik Dr. Amit Mhapushkar Dr. Anand Sabane	Oral Medicine and Radiology	Evaluation of the accuracy of a newly developed Intelligent software in predicting osteoporosis in women using digital OPGs
3	Dr. Amit Chaudhari Dr. Poonam Gupte	Periodontology	Prevalence of Prediabetes in patients suffering from Periodontitis and analysis of their microflora in saliva
4	Dr. Mayur Chaudhary Dr. Shweta Chaudhary Dr. Laxmi Lakade Dr. Rakhi Modak	Oral and Maxillofacial Pathology and Oral Microbiology	Medicolegal awareness among dental professionals in Pune, India: a questionnaire based study
5	Dr. Shweta Jajoo and Dr. Sneha Desai	Pedodontics & Preventive Dentistry	Comparative evaluation of flexural strength, wear resistance and micro-hardness of Zirconia Reinforced Glass Ionomer Cement, Silver Reinforced Glass Ionomer Cement and



			Conventional Glass Ionomer Cement: An in vitro study
6	Ms. Medha Kaushal Ms. Yashashree Marne	Orthodontics & Dentofacial Orthopedics	Evaluation of skeletal maturity and accuracy of age determination in local population using cervical vertebral bone age method and hand wrist – A retrospective radiographic study
7	Dr. Kenjale Manasi	Pedodontics & Preventive Dentistry	Assessment of enamel surface roughness and extent of resin tags after enameloplasty and pit and fissure sealant application using Ultrasonic oscillating Tips and conventional Low speed burs – an in vitro study
8	Dr. Tawde Mayuri	Pedodontics & Preventive Dentistry	Comparative evaluation of remineralization potential, pH change and effectiveness of alcoholic extract of cocoa powder and a fluoride remineralizing agent against S.mutans: An in vitro study
9	Dr. Kade Kimaya	Pedodontics & Preventive Dentistry	Comparative evaluation of the effect of different irrigating solutions on bond strength of obturating materials: An invitro study
10	Dr. Gholap Chaitanya	Pedodontics & Preventive Dentistry	Evaluation of the Histology of Carious Human Primary Incisor after treatment with 38 % Silver Diamine Fluoride (SDF)
11	Dr. Manasi Shimpi	Pedodontics & Preventive Dentistry	Evaluation of Knowledge, Awareness, and Occurrence of Facial and Dental Trauma in Children Practicing and Training in Martial Arts: A Survey
12	Dr. Soniya Raheja	Pedodontics & Preventive Dentistry	Awareness among Oncologists about Oral Changes following Chemotherapy in Leukemic Children and their Prevention: A Survey

Total number of PhD thesis approved 01

Total number of short studies approved 12

**Total number of projects approved 13**

## **Institutional Ethics Committee meeting**

**5<sup>th</sup> April 2019**

### **Short studies**

<b>Sr no</b>	<b>Name</b>	<b>Department</b>	<b>Title</b>
1	Dr Rajesh Kshirsagar –P.I. Dr Swapna Patankar Dr Amod Patankar	Oral and Maxillofacial Surgery	Analysis of Internees perception of Academics, Infrastructure and Support Systems of the Institute – A Questionnaire Based Study
2	Dr Alok Patel – P.I. Dr Preetam Shah Dr Chetan Bhat Dr Sanket Kunte	Pedodontics & Preventive Dentistry	Evaluation of the knowledge, attitude and practices of clinical preventive pediatric dentistry in general dental practitioners in Pune city: A cross sectional study
3	Dr Amol Jamkhande – P.I. Dr Saurabh P. Kakade Dr. Mahesh Khairnar	Pedodontics & Preventive Dentistry	A survey of use of social media in private practice by dentists in India
4	Dr Arti. R. Gachake –P.I. Dr Vasanthi Swami Dr U.B.Gajare Dr Darshana Mundhe Dr Pallavi Birajdar	Prosthodontics and Crown and Bridge	Evaluation of Awareness towards maintenance practices and treatment options among Removable partial and complete Denture Wearers in local population-A Questionnaire Based study
5	Dr Laxmi Lakade – P.I. Dr Shweta Chaudhary Dr Mayur Chaudhary Dr Rahul Lodaya	Pedodontics & Preventive Dentistry	Awareness and knowledge of eco-friendly dental office strategies among Indian dentist-A questionnaire based study
6	Dr Rakhee Modak –P.I. Dr Amit Mhapuskar Dr Mayur Chaudhary	Oral Medicine and Radiology	Evaluation of Transcutaneous Nerve Stimulation Therapy (TENS) for salivary flow in post-menopausal females-An In-Vivo Study

7	Dr Sujata Pinge –P.I. Dr Judy Koshy Dr Rajani Komble	Public Health Dentistry	Evaluation of awareness status and oral hygiene practice among school children in the age group 10-12 years
8	Dr Vaishali Joshi -P.I. Dr Samir Achyut Joshi Dr Amod Patankar Dr Swapna Patankar	Oral Medicine and Radiology	Evaluation of normal range of maximum mouth opening for local adult population
9	Dr Santosh Jadhav –P.I. Dr Abhijit Jadhav Dr Prakash Vhatkar	Oral Medicine and Radiology	Comparison of efficacy of pharmacotherapy with or without transcutaneous electric nerve stimulation(TENS) therapy in the management of temporomandibular joint disorder individuals
10	Dr Shivdas Mali –P.I. Dr Shubhangi Wadgaonkar Dr Meena Patil Ms Sadhana Gawade	Basic Medical Sciences	Evaluation of knowledge & awareness of prevention of Hepatitis B virus infection among dental students – Questionnaire based study

**Total number of projects approved**

**10**

## Institutional Ethics Committee meeting

**8<sup>th</sup> May 2019**

### Short studies

Sr no	Name	Department	Title
1	Dr Sarita Singh –P.I. Dr Abhijit Jadhav Dr Jyoti Mandlik Dr A.S. Sharma Dr Manjiri Khare	Conservative Dentistry and Endodontics	Comparative evaluation of effect of Ethylenediaminetetraacetic acid(EDTA), Chitosan and Electroconductive hydrogel on microhardness of root dentin and their efficacy for smear layer removal during endodontic treatment : An in vitro study
2	Dr Ashwini Gaikwad – P.I. Dr Varsha Pandit Dr Mrunal Shinde Dr Ajinkya Gharge	Conservative Dentistry and Endodontics	Comparative evaluation of the apical microleakage of retrograde cavities filled with Mineral trioxide aggregate(MTA), Biodentine(Calcium silicate based), Geristore(Dual cure resin based glass ionomer cement) – an in vitro study
3	Dr Shweta Chaudhary – P.I. Dr Laxmi Lakade Dr Mayur Chaudhary Dr Darshan Hiremath	Pedodontics and Preventive Dentistry	Comparison of Cameriere's method of age estimation with chronological age in children from the local population
4	Dr Anand Sabane – P.I. Dr Vinit Swami Dr Shailesh Deshmukh Dr Gauri Vichare	Orthodontics and Dentofacial Orthopedics	Comparison of maxillary and mandibular arch width and Bolton's ratio in Class II div-2, Class II Subdivision and Class II div-I malocclusions – An in vitro retrospective study
5	Dr Saurabh Khadelwal – P.I. Dr Rajshekhar Halli Dr Kiran Gadre Dr Shandilya Ramanojam	Oral and Maxillofacial Surgery	Comparative evaluation of modified arch bar with Erich's arch bar used for intermaxillary fixation in oral and maxillofacial surgery
6	Dr Priya Lele –P.I. Dr Namita Sharma Dr Rajendra Garud	Periodontology	Assessment of the soft tissue cover of the hard palate in the local population; an attempt to provide safe regions for harvesting palatal grafts

7	Dr Ajinkya Gharge – P.I. Dr Aniket Jadhav Dr Rajendra Daule	Conservative Dentistry and Endodontics	Comparison and evaluation of push out bond strength using three different bio-materials in an open apex – An in vitro study
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**Total number of projects approved**

**07**

All the meetings were conducted in a disciplined manner and with camaraderie. We thank all the ethics committee members and the Principal, BVDUDCH-Pune, for their support in conducting these meetings smoothly.

**Dr Revati Deshmukh**  
**Member Secretary**  
**Institutional Ethics Committee**

**Bharati Vidyapeeth Deemed University**

**Dental College & Hospital**

**Pune-Satara Road, Pune 411043**

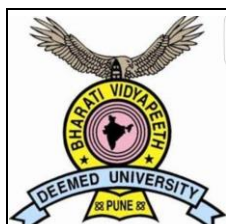
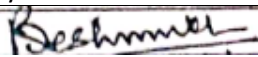
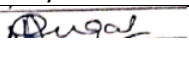
## **Standard Operating Procedures (SOP)**

**Bharati Vidyapeeth Deemed University**

**Dental College & Hospital - Pune.**

**Institutional Ethics Committee**

**[BVDUDC&H- PUNE- IEC]**

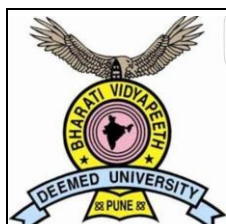
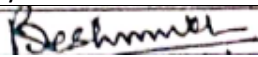
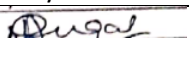
	<b>Institutional Ethics Committee SOP</b> <b>Trials on Vulnerable Population</b>	
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Reviewed by: Dr. Revati Deshmukh	Approved by: Dr. Ramandeep Duggal	
Sign: 	Sign: 	

## 1. Objectives of the Standard Operating Procedures:

The Standard Operating Procedures (which shall be referred to as SOPs' henceforth in this document) aim to define the procedures that **Bharati Vidyapeeth Deemed University Dental College and Hospital Pune – Institutional Ethics Committee** 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 Bharati Vidyapeeth Deemed University Dental College & Hospital, 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 Bharati Vidyapeeth Deemed University Dental College & Hospital, 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.

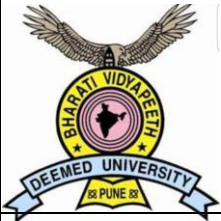
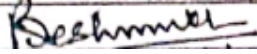
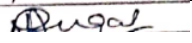
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Sign: 	Sign: 	

- 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 2<sup>nd</sup> 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. Composition of the BVDUDC&H- Pune- IEC - As per ICMR guidelines,**

- The BVDUDC&H- Pune- IEC shall be cross-disciplinary and multi-sectoral in composition.
- The Board shall consist of 7-12 members.
- A minimum of 5 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.



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Sign: 		Sign: 	

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:**

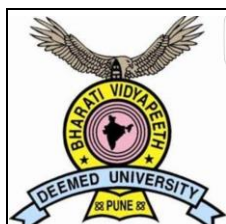
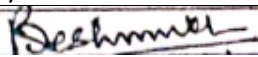
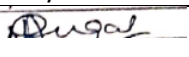
- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- New members will be identified according to the requirement i.e. as per the composition specified in section 7. 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

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Sign: 	Sign: 	

## 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.

### Secretary

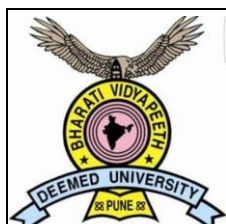
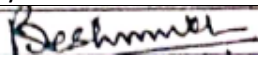
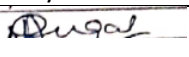
- The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all those concerned and shall maintain a copy of the minutes/proceedings of the meetings prepared after approval by the Chairperson, before communicating the same to the researchers. He/she 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.

### The 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.

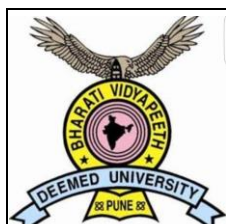
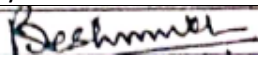
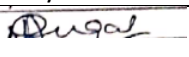
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- The administrative staff will report to the Chairperson and/or Member Secretary.
- The office timing for the administrative staff will be as per BVDUDC&H-Pune, rules & regulations.
- The administrative staff will avail leave as per BVDUDC&H-Pune, norms.

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

### **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 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 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.

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Sign: 	Sign: 	

## 6.b Terms of membership

- 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.
- 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 BVDUDC&H- Pune- IEC so that we have enough members to replace ones that have to step down.

## 6.c 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.

## 6.d Confidentiality

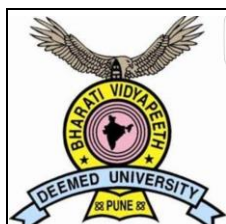
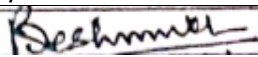
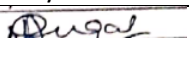
- All Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of IEC. The Members should not discuss matters related to BVDUDC&H- Pune- IEC deliberations with anyone other than other BVDUDC&H- Pune- IEC Members. All personal copies of documents and emails related to the proposal should be destroyed immediately.

## 6.e 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.

## 7. Quorum requirements

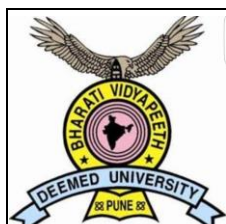
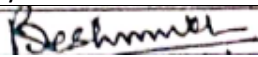
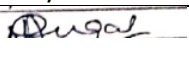
- A minimum of 6 Members are required to compose a quorum.

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Sign: 	Sign: 	

- All decisions should ideally be taken in meetings except in case of expedited review required in special circumstances (see pt. 14).

## 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.

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## 9. Application Procedures

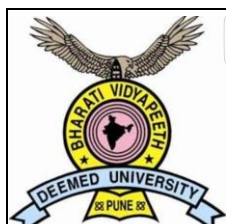
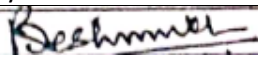
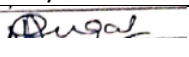
### 9.1 Who can apply :

- 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. 5,000 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.
- 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.

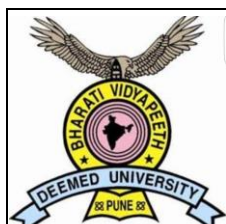
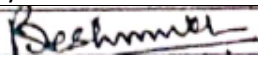
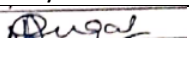


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Sign: 	Sign: 	

## 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.

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## 11. Review procedures:

### 11.1 Conduct of review:

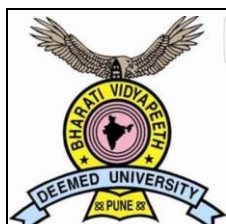
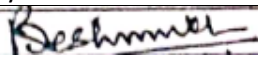
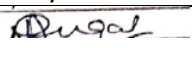
The BVDUDC&H- Pune- IEC will take care that special attention is given to the informed consent process, documentation, and the suitability and feasibility of the protocol.

- 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. Criteria for withdrawal of patients, suspending or terminating the study
- Management of research related injuries, adverse events and serious adverse events.
- 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.



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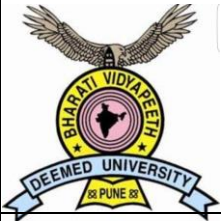
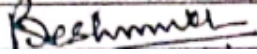
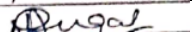
- Plans for data analysis and reporting, along with safety and quality assurance report(s).
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure of study sites.

### 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

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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 herewith**

- 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).

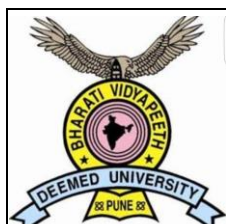
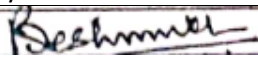
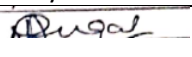
## **13. Appeal Procedures**

This procedure is

- 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.
- 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 s/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

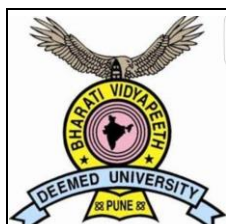
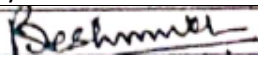
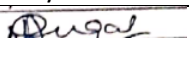
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recommendations the BVDUDC&H- Pune- IEC can make an amended decision. This decision cannot be appealed against, using the procedure described above

#### 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. Record keeping and Archiving

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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.

#### **16. Updating BVDUDC&H- Pune- IEC Members**

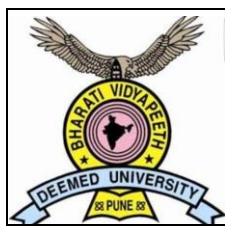
Any relevant updates/ guidelines in the processes of the BVDUDC&H- Pune- IEC shall be brought to the immediate attention of all Members. Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review by being updated with 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-**

[BVDUDC&H-Pune- IEC](#)



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1. Human Ethics guidelines, [www.icmr.nic.in](http://www.icmr.nic.in)
2. Standard operating Procedures, Human Ethics Committee, Tata Memorial Centre, Tata Memorial Hospital, <https://tmc.gov.in/research/pdf/TMC-HEC-SOP.pdf>
3. Standard operating Procedures, Human Ethics Committee, Sangtha, Goa, [http://sangath.com/images/file/SOPs\\_v4\\_15\\_april\\_2012.pdf](http://sangath.com/images/file/SOPs_v4_15_april_2012.pdf)
4. <http://www.sgpqi.ac.in/sop/main.htm>