To, The Principal, BVDU Dental College & Hospital, Pune-43

Subject: Report of Institutional Ethics Committee from <u>July 2019 to December 2019</u>

Respected Sir,

I am submitting herewith, the Report of Institutional Ethics Committee from <u>July 2019 to December 2019</u>.

This is for your information & perusal.

Sincerely,

Spwadgaenker

Dr. Shubhangi Wadgaonkar Member Secretary Institutional Ethics Committee

### Report

### (June 2019 - Dec 2019)

The ethics committee of Bharati Vidyapeeth Dental College was registered and reformed on the 20<sup>th</sup> December 2019 as "The Institutional Ethics Committee, Bharati Vidyapeeth Deemed University Dental College and Hospital – Pune (IEC-BVDUDCH-PUNE). It was reformed in accordance with Chapter-4 of the New Drugs and Clinical Trials rules, 2019 with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

The provisional certificate approved by DHR (file no: EC/NEW/INST/2019/329 dated 20<sup>th</sup> December 2019), in exercise of the powers conferred by sub-rule (3) of rule 17 of the Chapter-4 of the New Drugs and Clinical Trials rules, 2019, and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR)

#### Aim:

1. To analyse research proposals of PhD, Post-graduate students and Staff members in a manner that it is directed towards the increase of knowledge about the human conditions, with respect to dignity, rights, benefit and justice to the participating human volunteers.

### **Objectives:**

- 1) To acquire competent review, which is free from any bias and influence which could affect its objectivity and interest of participating subject.
- 2) To ensure that universal ethical values and international scientific standards are expressed in accordance with local community values and customs.
- 3) To follow the general principles of essentiality voluntariness, informed consent and agreement.
- 4) To ensure principles of non-exploitation, privacy and confidentiality. Principles of precaution and risk minimisation, professional competency, accountability and transparency.
- 5) To ensure principles of responsibility public domain and compliance are observed.

The committee was reconstituted in 2019-20

The composition of the IEC-BVDUDCH, Pune during 2019-20 is as follows:

Sr No.	Name of Faculty	Designation	
1	Dr. Sahana Hegde	Chair person	
2	Dr. S.P Wadgaonkar	Member Secretary	
3	Adv. Sarita Dugane	Member – Legal expert	
4	Mrs. Asawari Joshi	Member – Social scientist	
5	Dr. Usha Varghese	Member – Social worker	
6	Dr.Supriya Bhalerao	Member – Subject expert (Ayurved)	
7	Dr. Vanita Patwardhan	Member – Lay person	
8	Dr. Jayashree Dawane	Member – Subject expert (Pharmacology)	
9	Dr. Vasantha	Member – Subject expert (Prosthodontics)	
10	Dr. Jyoti Mandilik	Member – Subject expert (Conservative dentistry)	
11	Dr. Amit Mhapuskar	Member – Subject expert	
		(Oral Medicine and Radiology)	
12	Dr. Gauri Vichare	Member – Subject expert (Orthodontics)	
13	Dr. R. Shandilya	Member – Subject expert (Oral Surgery)	
14	Dr. Vishaka Patil	Member – Subject expert (Periodontology)	
15	Dr. Surekha Chavan	Member – Subject expert	
		(Oral Pathology & Microbiology)	
16	Mrs Rajeeta Joseph.	Co-ordinator	

The committee conducted ethical clearance for two interns (Under graduate students) and two staff members.

#### Code of Ethics for Research

- In accordance with Chapter-4 of the New Drugs and Clinical Trials rules, 2019 with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR), dated 20<sup>th</sup> December 2019. BVDUDCH Pune, Institutional Ethics Committee was registered with provisional registration certificate as approved by DHR (file no: EC/NEW/INST/2019/329 dated 20<sup>th</sup> December 2019),
- In exercise of the powers conferred by sub-rule (3) of rule 17 of the Chapter-4 of the New Drugs and Clinical Trials rules, 2019, and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR)
- Rules and regulations are followed according to the office of Department of Health and Family Welfare, Government of India, Department of Health Research, 2<sup>nd</sup> floor, IRCS Building, New Delhi 110001. Approval of the research project is in accordance to the format suggested by DHR, which includes an undertaking by the investigator to follow all the rules and regulations. The IEC approves the project by giving reviewers comments in the form of an approval letter signed by the Member Secretary.
- Conflict of interest and letter of confidentiality duely signed by all Ethics committee members is strictly maintained.
- It is compulsory to submit all clinical trials studies to Indian safety drug data or literature.
- In case of animal studies, approval of separate Animal Ethical Committee is a must.
- As per the guidelines of Ethical Committee, detail information sheet and consent form in English and vernacular language is made compulsory for faculty and students before taking patient as a subject for research.
- Meetings are conducted every 8 months once the institutional research committee approves the projects

Date of the Meeting – 06-12-2019 Venue – Conference room Time – 9:30 am onwards

#### Agenda:

- 1. To discuss 02 research proposals submitted by the staff member of the Department of Oral Medicine and Radiology
- 2. To discuss 02 research proposals submitted by the PhD Scholar from the Department of Oral Pathology and Microbiology
- 3. To discuss 04 research proposals submitted by the under graduate students (Interns)

#### Minutes of the meeting:

- 1. This was the first meeting for the academic year 2019-20.
- 2. 8 Members were present for the meeting.
- 3. Dr. Usha Vargese and Dr. Jayshree Dawane were granted leave for absence. Other subject experts from our college were on winter vacation except Dr. Vasantha, Dr. Jyoti Mandlik and Dr. Shubhangi Wadgaonkar.
- 4. Felicitation and welcome to all new members was done by Principal Dr. Rajesh Kshirsagar.
- 5. 2 research proposals of undergraduate students (Interns) were discussed and approved by Ethics Committee.
- 6. 2 research proposals of undergraduate students (Interns) were under consideration with necessary changes.
- 7. 02 research proposals submitted by the staff members and 02 research proposals submitted by the PhD Scholars were discussed and asked to resubmit with changes.

#### **Resolutions:**

- 1. The next meeting of the IEC was decided to be conducted on 22-01-2020 at 9:30 am onwards, venue being the same.
- 2. It was decided that the resubmitted proposals and research proposals (Dissertations) from the Department of Oral Surgery, Orthodontics and Paediatric Dentistry will be discussed in the next meeting.

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Dr. Shubhangi P. Wadgaonkar Member Secretary Institutional Ethics Committee

### Bharati Vidyapeeth Deemed University Dental College & Hospital, Pune- 411043

Ref - BVDUDC&H-IEC-1310/2019-2020

Date - 06/12/2019

### IEC Meeting on 6/12/19

### **Attendance of Members**

Sr No.	Name of Faculty	Designation	Signature
1	Dr. Sahana Hegde	Chair person	De
2	Dr. S.P Wadgaonkar	Member Secretary	Sprandgumlen
3	Ady. Sarita Dugane	Member – Legal expert	Sylve
4	Mrs. Asawari Joshi	Member – Social scientist	Asavas
5	Dr. Usha Varghese	Member – Social worker	
6	Dr.Supriya Bhalerao	Member – Subject expert (Ayurved)	Gladouge -
7	Dr. Vanita Patwardhan	Member – Lay person	Vanila Patra
8	Dr. Jayashree Dawane	Member – Subject expert (Pharmacology)	
9	Dr. Vasantha	Member – Subject expert (Prosthodontics)	Masar A.
10	Dr. Jyoti Mandilik	Member – Subject expert (Conservative dentistry)	
11	Dr. Amit Mhapuskar	Member – Subject expert (Oral Medicine and Radiology)	
12	Dr. Gauri Vichare	Member – Subject expert (Orthodontics)	
13	Dr. R. Shandilya	Member – Subject expert (Oral Surgery)	
14	Dr. Vishaka Patil	Member – Subject expert (Periodontology)	
15	Dr. Surekha Chavan	Member – Subject expert (Oral Pathology & Microbiology)	
16	Mrs Rajeeta Joseph.	Co-ordinator	Vamely