


**Bharati Vidyapeeth (Deemed to be University),
College of Nursing, Pune
Pune - Satara Road, Dhankawadi,
Pune 411043**

**Standard Operating Procedures
(SOP)**

**Bharati Vidyapeeth (Deemed to be University),
College of Nursing, Pune-Ethics Committee
(BVDUCON, Pune-EC)**

VERSION-I

Dated – January 2021


Principal
Bharati Vidyapeeth (DU)
College of Nursing, Pune-43

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


10. Vulnerability

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

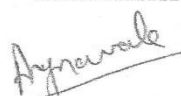
1. COVID-19 patients may be additionally vulnerable of being stigmatized due to the contagious nature of the disease. Also at risk are health care workers in COVID-19 hospitals including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers etc.
2. Socially, economically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


References

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


Principal
B.V. D'S. Vidyapeeth (DU)
College of Nursing, Pune

Chairman
Institutional Ethics Committee
B.V. D'S. College of Nursing,
Pune - 411 013


Member Secretary
Institutional Ethics Committee
B.V. (DU) College of Nursing,
Pune - 411 013


Dr. S. R. Agarkhedkar
M.D. (Paed)
Professor & Head, Paediatrics
Regd No.- 38667 (MMC)

File No. - EC/NEW/INST/2021/1503



**Government of India
Ministry of Health & Family Welfare
Department of Health Research**

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 23-Jul-2021

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter-IV of the New Drugs and Clinical Trials Rules, 2019.

Name : Bharati Vidyapeeth Deemed to be University, College of Nursing, Pune-
Ethical Committee
Address : Bharati Vidyapeeth Deemed to be University, College of Nursing, Pune,
Pune- Satara road, Dhankawadi Pune, Pune, Maharashtra - 411043
Contact No: 02024372496
Fax : 02024364515

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., 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).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU
NAGAR
(Anu Nagar)

Digitally signed
by ANU NAGAR
Date: 2021.07.23
14:22:34 +05'30'

Joint Secretary
Department of Health Research
Designated Authority

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairperson Sharad Agarkhedkar, Dr.D.Y.Patil Medical College ,Hospital And Research Centre, Pune, Pune, Maharashtra, India - 411018
2. Name and address of the office : of the Ethics Committee* Bharati Vidyapeeth Deemed to be University, College of Nursing, Pune- Ethical Committee, Bharati Vidyapeeth Deemed to be University, College of Nursing, Pune, Pune- Satara road, Dhankawadi, Pune, Pune, Maharashtra - 411043
Contact No. : 02024372496 Fax No. : 02024364515

3. Names, address, qualifications & designation of all the members of the Ethics Committee*

S.No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail and mailing address	Designation/ role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Sharad Agarkhedkar	MBBS (Pediatric)	Dr.D.Y.Patil Medical College , Hospital And Research Centre	Mobile: 9822030122, email: ashalaka@gmail.com Add: D1, Hill View Residency, Pune, Pune, Maharashtra-411048	Chair Person	No
2	Dr. Anita Yuvaraj Nawale	BSc (M.Sc. Nursing, Ph. D. Nursing)	Bharati Vidyapeeth (Deemed To Be University), College Of Nursing, Pune	Mobile: 9561055493, email: anitanawale@gmail.com Add: Aaswad Park, Flat No. 4, Dattnagar Rd., Pune, Pune, Maharashtra-411046	Member Secretary	Yes
3	Dr. Vijay Haribhau Mate	MBBS (MD-Pharmacology)	BHARATI VIDYAPEETH DEEMED TO BE UNIVERSITY MEDICAL COLLEGE PUNE	Mobile: 9422012517, email: vijayhmate@gmail.com Add: D-501, Shree Rajyog Society, Pune, Pune, Maharashtra-411037	Basic Medical Scientist	No
4	Dr. Pailavi Bajpayee	MBBS (MD/MS - Anatomy)	Dr. D Y Patil Medical College, Pimpri, Pune	Mobile: 9860833756, email: vinks162@gmail.com Add: E3/ 10, Pune, Pune, Maharashtra-411022	Basic Medical Scientist	No

5	Dr. Purwa Doke	MBBS (MD - General Medicine)	BHARATI VIDYAPEETH DEEMED TO BE UNIVERSITY MEDICAL COLLEGE PUNE	Mobile: 9823060852, email: purwadoke@gmail.com Add: Flat No. 1004, Shreenath Chandrangan, Pune, Pune, Maharashtra-411043	Clinician	No
6	Ms. Sumati Unkule	BA (M.A. Sociology, M. Phil. Sociology)	The Bishops Junior College, Camp	Mobile: 9923475006, email: sumatiu@gmail.com Add: C/O Mr. Aseem Tribhuvan, 12B, Manish Apt., Pune, Pune, Maharashtra-411007	Social Scientist	No
7	Ms. Sarita Prakash Dugane	LLB (Master of Laws (LL.M.))	Bharati Vidyapeeth New Law College Pune	Mobile: 9922341552, email: sarita19dugane@gmail.com Add: C-104, Mohite Township, Pune, Pune, Maharashtra-411051	Legal Expert	No
8	Ms. Varsha Rajiv Jogdeo	BA (T.T.C.)	S. P. M. English Medium School, Pune	Mobile: 9527447427, email: varsha_jogdeo@rediffmail.com Add: 77, 4th Floor, Wing No. 4, Anand Park, Pune, Pune, Maharashtra-411051	Lay Person	No
9	Mr. Rajkumar Yashvant Yadav	BA (M.A.)	Bharati Vidyapeeth (Deemed To Be University), College Of Nursing, Pune	Mobile: 9766658517, email: yadavaryan30@gmail.com Add: Flat No. 103, Chinmay Vaishwa, A Wing, Pune, Pune, Maharashtra-411046	Other Supporting Staff	Yes
10	Mr. Stawan Uttam Chougule	BSc (M.Sc. Nursing)	Bharati Vidyapeeth (Deemed To Be University), College Of Nursing, Pune	Mobile: 9850460817, email: stawanc@gmail.com Add: 105, Rajni Corner-1, Nr Tuljha Bhavani Mandir, Pune, Pune, Maharashtra-411043	Member	Yes

11	Dr. Jyotsna Rajendra Deshpande	BSc (Nursing)	Sushrusa Institute Of Nursing Sciences, Daund	Mobile: 9763328546, email: jyotsnadeshpande48@gmail.com Add: C- 11, SidhiVinayak Vihar, Pune, Pune, Maharashtra-411046	Scientific Member	No
12	Dr. Bhagyashree Anil Jogdeo	BSc (M.Sc. Nursing, Ph. D. Nursing)	Bharati Vidyapeeth (Deemed To Be University), College Of Nursing, Pune	Mobile: 9922062740, email: bjogdeo@gmail.com Add: 1314/ 3, Sadashiv Peth, Pune, Pune, Maharashtra-411030	Scientific Member	Yes
13	Ms. Saraswati Gajanan Garad	BSc (M.Sc. in Biometry)	Retired	Mobile: 9552539193, email: sggarad@hotmail.com Add: A9, S1-S2, Planet Millenium, COP Housing Society, Pune, Pune, Maharashtra-411027	Scientific Member	No
14	Dr. Khurshid Sultan Jamadar	BSc (M.Sc. Nursing, Ph. D. Nursing)	Bharati Vidyapeeth (Deemed To Be University), College Of Nursing, Pune	Mobile: 9890771989, email: khurshid2002@gmail.com Add: Sukhwani Campus, Pune, Pune, Maharashtra-411018	Scientific Member	Yes

4. Commitments:

(1) The Committee shall review and accord its approval to a biomedical research and also carry ongoing review of the study at appropriate intervals, as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants - ICMR for safeguarding the rights, safety and well- being of the research participants.

(2) In case of any serious adverse event occurring to research participants during the research study, the Committee shall analyze and forward its opinion as per procedures specified under National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

(3) The Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of biomedical and health research.

(4) We agree to maintain adequate and accurate records after the completion or

termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies).

Member Secretary
(Signature of the ~~Chairperson~~)

Date: 3/6/2021

Agarwal
Member Secretary
Institutional Biosafety Committee
BPPS
Regd No. 1243

Chairperson
(Signature of the ~~Member secretary~~)

Date: 3/6/2021

Agarkhedkar
Dr. S. R. Agarkhedkar
M.D (Paed)
Professor & Head, Paediatrics
Regd No.- 38657 (MMC)

Chairman
Institutional Biosafety Committee
Institutional Biosafety Committee

