

Prof. Dr. Shivajirao Kadam

Chancellor

Prof. Dr. M. M. Salunkhe M.Sc., Ph.D., F.R.S.C.

Vice Chancellor

Bharati Vidyapeeth

(Deemed to be University)
Pune, India.

Founder Chancellor : Dr. Patangrao Kadam

MEDICAL COLLEGE, PUNE

★ Accredited with 'A\*\* Grade (2017) by NAAC ★

\* Accredited with A. Grade (2017) by NAAC 

\* Category-I University Status by UGC \*

★ NIRF Ranking - 62 ★

"Social Transformation Through Dynamic Education"



Dr. Vishwajeet Kadam B.Tech., M.B.A., Ph.D. Pro Vice Chancellor

Brig. (Retd) Dr. N. S. Mani

Principal

Date:08 08 2020

Ref. No.: BVDU/MC/1289/20-21

### Medical Education Unit Notice

To,
Head of the Department
B V U Medical College,
Pune-43.

Sub: Research Methodology Workshop (RM WS) for JR 1 (2020 admissions):

Batch 1: 17<sup>th</sup> Aug Batch 2: 18<sup>th</sup> Aug Batch 3: 8<sup>th</sup> Sep

The Medical Education Unit of our college, along with the Department of Community Medicine, is organizing a Workshop on Research Methodology for newly enrolled PG Students (Degree, Diploma, M.Sc.). It is a 1-day workshop which will be conducted in three small batches of 40 students each in order to accommodate all PG students admitted during year 2020-2021 with due COVID precautions.

It is mandatory for all JR 1 students to attend this Workshop and attach the Certificate of Attendance while submitting Dissertation Proposals to the Ethics Committee. In order to benefit maximally from this Workshop, they are expected to bring the first draft of their proposed Dissertation topic with them.

Kindly ensure that all your PG students attend with either of the batches:

Batch 1: 17th Aug Batch 2: 18th Aug Batch 3: 8th Sept

Venue: Auditorium, 3rd Floor, BVDU Medical College

Time: 9.00 am to 5.00 pm

Please depute JR 1 students from your department to attend the Workshop, ensuring equal distribution in the 3 batches. They should be kept totally free from the departmental duties on the respective days. Certificate will be awarded only to those who actively participate in the entire Workshop. Working lunch will be arranged for the participants.

Please share this notice with your students. Please ask them to register on line by 11th August, using the link shared on the HoD group,

Any PG Teachers desirous of attending the RM WS and who will be able to attend the entire workshop, should also register as observers, indicating the batch they would attend with.

The batch allocation letter (attached with this notice) from Heads of the Departments should reach the Head, Dept of Community Medicine by 11th August.

NS NOW

Bharati Vidyapeeth (Deemed to be University)

Pune-Satara Road, Pune - 411 043 (INDIA)

Tel: +91-24-edirad2 Col 38561 | Fax: +91-20-24372175 | E-mail: bvumedicalpune@gmail.com | Web: www.mcpune.bharatividyapeeth.edu

# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY LECTURE SERIES for JR 1-2020

## BATCH 1 - MONDAY, 17 August 2020

NO	NAME	Department	Mobile no	SIGN MORNING	SIGN AFTERNOON
1 / (DR. JOSA	MIRIAM.  Dr. Josna Fernandes  A MIRIAM FERNANDES)	Anaesthesia	9886632202	J.M. Gernande	J.M . Ferner
2 /	Dr.Tara Kiran A	Anaesthesia	7760011201	Tograkiran.A	Jagaki san. A
3 -	Dr.Merary M	Anaesthesia	9840484495	M.	lug.
4 -	Dr.Kenchey Kaushal	Anaesthesia	9032113377	(glad	Olul
5/	Dr.Nirmal Kumar	Anaesthesia	9080158714	ath	Que
6_	Dr.Shantanu singhal	Cardiology	8077749912	1 woulder.	12-ostor.
7-	Dr Ankita Phade	Dermatology	8275896469	Afflude	ARPhade
8 -	Dr.Prerana Misal	Dermatology	8055487220	Risal	Posal
9_	Dr. Charchit Bansal	Emerg. Med.	8817587910	found.	(AL)
10_	Dr.Kapadia Saurin	Medicine	9033284057	Jawie	fare
11/	Dr.Shantanu Kanitkar	Medicine	8308592201	Shounds	Stands
12,	Dr.Vangala Kumar	Medicine	8142525678	ydes	USD
13,	Dr. Yashodeep Girwalkar	Medicine	9960750971	dr.	dri
14/	Dr.Rajal Dave	Microbiology	8177820784	(ALD)	(Ab) -
15	Dr. Anuja Sachapara	OBGY	9265072176	Anlacherter	Ab

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NO	NAME	Department	Mobile no	SIGN MORNING	SIGN AFTERNOON
16	Dr.Anisha Singh	OBGY	7565863000	Austra,	Anisha?
17,	Dr.Donthireddy Laxmi Sahithi	OBGY	8179872678	Sales	Sel
18,	Dr Kalyani Lohokare	Ophthalmology	7507192261	Agrine	watte
19	Dr.Murti Vimawala	Ophthalmology	9712901340	My	8
20,	Dr.Aghara Denish	Orthopaedics	8128619907	Jaich .	+ origh
21	Dr.Jadeja Rudraraj	Orthopaedics	7665406737	Prof	2007
22/	Dr.Akash Mantri	Orthopaedics	7020443112	An.	Ath.
23	Dr.Nukala Sita Ram	Paediatrics	9704718470	Wastale	n. Pastel
24	Dr.Hitin choudary	Paediatrics	9542129298	Hitin	tethin
25,	Dr.Sampathi Venkatesh	Paediatrics	7386589658	s. venberh	S. Vembeter
26	Dr.Anisha Reddy	Paediatrics	7259630135	Ante	tout.
27	Dr.P V Satyanarayana	Paediatrics	8374482839	Fig-furtion	Properties
28	Dr. Dwepa Parikh	Pathology	9662731002	life	200
29	Dr.Tanaya kulkarni	Pathology	9921757353	4	4
30	Dr.Rohan waykole	Pathology	7588193991	Par	20

NO	NAME	Department	Mobile no	SIGN MORNING	SIGN AFTERNOON
31/	Dr.Zeel manoj Patel	Pathology	7574980017	@will.	Campell.
32/	Dr.Anjalee Nagda	Psychiatry	9518728517	Alvara	time
33/	Dr.Anshumi Bhattacharya	Psychiatry	9503299864	(Ab)	(AB)
34	Dr Rajput Avani Surendra	Pulmn. Med	9823370974	Quality	ander
35	Dr.Md Khaja Mohiuddin	Radiology	7993878724	let 3	(e)
36	Dr Devdikar Tejas Rajendra	Radiology	7741000724	Neville	allardia
37/	Dr.Nivedita Ghule Patil	Radiology	9623200999	West	Mah'
38	Dr.Anmol Dhawan	Radiology	7507498850	Solhawan	(A500)
39	Dr.Chavan Rajpal Subhash	Radiology	9049899809	Alahan	Phalai
40	Dr.Shivani Nitin pawar	Radiology	9881409689	Id.	8
41	Dr.Harpreet Kaur Malhotra	Radiology	8090670701	1 aupocet	Nauprest
42	Dr.Vyas Achal Bharatbhai	Surgery	9662261765	Ames	Avyes
43	Dr.Ujwal Mukund Badave	Surgery	8159766160	on	over
44	Dr. Abhishek Gupta	Surgery	9415554366	Mhofit	Allush

Batch 3

NO	NAME	Department	Mobile no	SIGN MORNING	SIGN AFTERNOON
45	Dr. Bhagyalaxmi Paramshetti	Medicine			
46	Dr. Ujwal Kumar Akula	Medicine			1
45	Dr. Karan Singh	Medicine	7507791310	Karan	Varoy

146. Dr. vjwal

Kumal AKULA medicine 9000035683 ( )

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# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY LECTURE SERIES for JR 1-2020

### BATCH 1 - Monday, 17 August 2020

### Venue: 3<sup>rd</sup> Floor Conference Hall, Bharati Medical College

	Time	Event	Faculty
	8.45 - 9.00 am	Registration	
05-9:20	9.00 - 9.15 am	Introduction of participants	Dr. Lalna Takle
20 - 1:32	9.15 - 9.30 am	Objectives of Workshop	Dr. N. S. Mani
	59.30 - 9.50 am	Ethical Issues with focus on Patient information sheet and consent form	Dr. Jyoti Shetty
56 - 10:24	9.50 - 10.20 am	Formulation of hypothesis, research questions & objectives	Dr Kavita Srivastava
10	10.20 -10.30 am	Tea la	
140	10.30 – 12.00 pm	Research Designs – 1.Descriptive studies, Analytical studies  2.Experimental Studies(RCT)	1.Dr P.P. Doke 2.Dr. S P Gorthi
11:52 :00	12.00 – 12:30 pm	Assessing Validity & Reliability of Diagnostic & Screening Tests	Dr J S Gothankar
7-8	12.30 – 1.00 pm	Tools for Data Collection	Dr P D Pore
1.	1.00 - 1.45 pm	Lunch Break	remouse land
1-3:15	1.45 - 3.15 pm	Role of statistics in Research Methodology: -Sampling techniques, sample size estimation, power analysis.  Preparation of master chart, Data types & writing, Proposed statistical analysis in the protocol	Mr. Rupesh Deshmukh,
5-4:04	3.15 – 3.45 pm	Literature search	Dr Shiva Iyyer
H:53	3.45 – 4.15 pm	References	Dr. Medha Puranik
15-	4.15 – 4.45 pm	Writing research protocol with focus on methodology	Dr. N. S. Mani
4.30	4.45 – 5.00 pm	Self-Guided Work	All facilitators

# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY LECTURE SERIES for JR 1-2020

## BATCH 2 - Tuesday, 18 August 2020

### Venue: 3<sup>rd</sup> Floor Conference Hall, Bharati Medical College

	Time	Event	Faculty
	8.45 - 9.00 am	Registration	
65-9:19	9.00 - 9.15 am	Introduction of participants	Dr. Lalna Takle
	9.15 - 9.30 am	Objectives of the Workshop	Dr. N. S. Mani
289:5	9.30 - 9.50 am	Ethical Issues with focus on Patient information sheet and consent form	Dr. Jyoti Shetty
53 -	9.50 - 10.20 am	Formulation of hypothesis, research questions & objectives	Dr Kavita Srivastava
10:38	10.20 10.20	Tea matiscolla quora ao enibrocab posquitos	deng - V
:39 -	10.30 – 12.00 pm	Research Designs – 1.Descriptive studies, Analytical studies  2.Experimental Studies(RCT) #:15 - 12:10	1.Dr P.P. Doke 2.Dr. S P Gorthi
:10-	12.00 – 12:30 pm	Assessing Validity & Reliability of Diagnostic & Screening Tests	Dr. J S Gothankar
47-	12.30 – 1.00 pm	Tools for Data Collection	Dr P D Pore
	1.00 - 1.45 pm	Lunch Break	
50 -	1.45 - 3.15 pm	Role of statistics in Research Methodology: -Sampling techniques, sample size estimation, power analysis.  Preparation of master chart, Data types & writing, Proposed statistical analysis in the protocol	Mr. Rupesh Deshmukh,
25-	3.15 – 3.45 pm	Literature search	Dr Shiva Iyyer
4:55	3.45 – 4.15 pm	References	Dr. Medha Puranik
15 - 4:35	4.15 – 4.45 pm	Writing research protocol with focus on methodology	Dr. N. S. Mani
M.33	4.45 – 5.00 pm	Self-Guided Work	All facilitators

# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY WORKSHOP - I 2020 for JR 1

# BATCH 2 - TUESDAY, 18 August 2020

	NO	N	ame	Department	N	Nobile no	Sign Morning	Sign Afternoon
	1	D	r.Patel Nelka lukeshkumar	Anaesthesia •		8128658765		000
1,3			r.Suhail ashraf	Anaesthesia		7907154962	and the state of the	
dr3			or Aishwarya Shrinivas Deshmukh	Anaesthesia		8217474217	As Destuded	Manual
	3		or.Pallavi Singh	Anaesthesia		9890959845	7.5ingh	P. Singh
			Dr.Shreshtha Kawathekar	Anaesthesia		7389899770	Kewatul	P. Singh
		T	Dr.Sagar jaiswal	Dermatology	_	9619341145	Logar	De O
		7	Dr. Saloni Sawarthia	Dermatology	-	963248517	Salar	A L
		8	Dr.Jerry Mathew	Emergency Medicine	•	949504278	· Jem	Jenny
		9	Dr. Simran Sidhu	Ent -		863073729	3 Sinsolid	5 208
		10	Dr.Bhagyalaxmi Paramshetti	Medicine	1	7507919625	3 shotti. 51 Dyaliku	Hal Toyoti his
		11	Dr. Dyuti Mittal	Medicine	-	981967796	51 Dyour	logic
el.	5_	12	Dr. Meghana Nadagauda	ar Medicine		Deposition as		20.
odel.		13	40	Medicine	,	7	Rala	Halo.

NO	Name	Department	Mobile no	Sign Morning	Sign Afternoon
14	Dr.Pooja Dholakiya	Medicine	9428 03440	1 10	0
15	Dr. Ashwin Bankar	Medicine _	7892102831	al	the state of the s
16	Dr. Sonali Sawarthia	Medicine •	9967561975	In.	ho
17	Dr.Bhuvana Shanti Kollu	OBGY	9000577323	Sharte	Thati
18	Dr.Mali Vishal	OBGY -	9904055576	Charre	Der
19	Dr.Priyanka Deshmukh	Ophthalmology •	9892750630	de.	2
20	Dr.Nikhil Parashar	Ophthalmology /	9810984001	Willel	ishhil
21	Dr Atul Keswani	Orthopaedics •	8668495704	Je-	F
22	Dr.Dona Mariyam Sabu	Paediatrics	7795800127	Port.	Part.
23	Dr.Niyati Shah	Paediatrics /	7875611252	Neshah	What
24	Dr.Praharini CB	Paediatrics •	9035485330	feal:	Redi
25	Dr.Anu Tresa E	Paediatrics /	8220480801	Soludies .	2 On Alosa
26	Dr.Vrushali Kore	Paediatrics /	8497093033	Most	Mod

18th August 2020. Sign Sign Afternoon Morning Mobile no Department Name NO 7977682812 Dr Annu M Singh Khokhar Pathology 27 8806178118 Pathology Dr.Nishtha Danu 28 8460210038 Pathology Dr. Viyati Vithlani 29 7666930636 Pathology Dr. Amrutraj Patil 30 akh 3 9892277622 Pharmacology Dr.Rahee Borulkar 31 9866342239 Psychiatry Dr.Koduri Nityasree 32 9.19762E+11 Radiology Dr. Himanshi Singhal 33 7768982265 Radiology Dr. Prerna Malik 34 Dr.Moradiya 9033526411 Radiology Priyankkumar 35 8077501440 Radiology Dr.Rohit Pruthi 9535827770 Radiology Dr.T Sai Sree Lalini 37 8446557744 Radiology Dr.Ishita Seth 38 7500800506 Surgery Dr. Ashmita Gaur 39 7218872195 Surgery Dr.Ankith Pemmasani 40 7893621097 Surgery Dr. Tata Sonia 41

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OBGY .

Surgery

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DR. SHREYA SHARMA .U.

Dr.Sumit Ramchandra

# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY LECTURE SERIES – I 2020 for JR 1

## BATCH 3 - TUESDAY, 08 September 2020

	Full Name	Department	Morning	Afternoon
1 .	Vennam Venkata Naga Sowmya	Anaesthesia	&i.	Shi
2 *	Rohan R Thimbare	Anaesthesia	200	a allen
3 '	Akshay Shivajirao Chavan	Anaesthesia	(S)	Ber
4 1	Suhail Ashraf	Anaesthesia	uhail	Mail
5	Abhinav Mohabey	Cardiology	Bra	P.S
6.	Brinda Rana	Emergency Medicine	Godono	Polare
7	Krutika Vinay Yadav	ENT	Dur	K
8 .	Aviroop Saha Roy	Ent		***
9.	Mehta Parth	Medicine	0	
10 -	Nishtha Pansari	Medicine	MUY	New,
> 11	Nisarg Anil Momale	Medicine		
12	Nupoor Dandavate	Medicine	W.	· D.
<ul><li>13</li></ul>	Meghana Nadagaudar	Medicine	Oneghan Dingank	· Meghens
<b>•</b> 14	Priyanka Sawarthia	Medicine	Pringande	Pingand

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8th September 2020

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15	Komal vasant Gayakwad	Microbiology		
<b>-</b> 16	Umratkar Savita Kisan	Microbiology	Monutatkar	Minratka
47	Polareddy Preethi Reddy	Obsteritics and gynaecology	Powettin	Preethod
_ 18	Pentala Sai Aparna	Obstetrics and gyneacology	Asarwa	Apanso
<b>-</b> 19	Safwan Makbulhushen Lamba	Ophthalmology	Sof.	-500-
, 20	Shubham Lodha	Orthopaedics	Shulland	Studians
, 21	Kushagra Kaushik	Orthopaedics	No to	Johnshy
22	Prateek Singh Randhawa	Orthopaedics	Volver	Rolof
23	Chitturi Yashwanth	Orthopedics	Cath	( Sperior
24	Swapnil Rananaware	Paediatric	Lapul	Jugar
• 25	Zainab S Nandarvawala	Paediatrics	Laural	Found
26	Hema Priya R	Paediatrics	Blend	Dent
27	K Bhavana	Paediatrics	Bhamb	Ann
28	Dr Tanvi Bafna	Paediatrics	Comi	Qui.

	3			8th Septe	ember 2020.
	29	Anju Rose	Pathology	24 ·	Zord
	- 30	Mashru Denish Rajeshkumar	Pathology	Jenish.	Denon
,	31	Archana biyani	Pathology	dela	Arha
	32	Dr Lokesh Kumar	Pathology	-1gup[	-raupl.
	- 33	Pratiksha Dhamal	Pharmacology	Phimey_	phane)
the coming	34	Avinash Sarak	Pharmacology		
No	35	Rahee Borulkar	Pharmacology	Tour bar	Demilar
	36	Anshumi Bhattacharya	Psychiatry	Mattachary	12 Shatta change
	37	Kanika Juneja	Radiodiagnosis	Carre	and a
	38	Kamesh MB	Radiodiagnosis	kalis.	Je lin
-	39	Siddhartha Paturi	Surgery		
	40	Karan Dharamsi	Surgery	Vas	Va.
Nekra	41	Nihal A Handigol	Surgery		

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(Ph. -9620791557)

# Department of Community Medicine & Medical Education Unit Bharati Vidyapeeth (D.T.U) Medical College, Pune RESEARCH METHODOLOGY LECTURE SERIES for JR 1-2020

### BATCH 3 - Tuesday, 8 September 2020

### Venue: Ground Floor Auditorium, Bharati Vidyapeeth DTU Medical College, Pune

	Time	Event	Faculty				
	8.45 - 9.00 am	Registration					
7:50= 9:20	9.00 - 9.15 am	Introduction of participants	Dr. Lalna Takle				
21 + 9:34	9.15 - 9.30 am	Objectives of Workshop	Dr. N. S. Mani				
:35+10:00	9.30 - 9.50 am	Ethical Issues with focus on Patient information sheet and consent form	Dr. Neeta Hanumante				
1:01 +10:38	9.50 - 10.20 am	Formulation of hypothesis, research questions & objectives	Dr. Kavita Srivastava				
2:50 ÷	10.20 -10.30 am	Tea					
0:50+11:29	10.30 – 12.00 pm	Research Designs 1. Observational Studies 2. Experimental Studies	1. Dr P.P. Doke 2. Dr S P Gorthi				
2:11+12:40	12.00 – 12:30 pm	Assessing Validity & Reliability of Diagnostic & Screening Tests	Dr. S. K.Murarkar				
2:40 71:19	12.30 – 1.00 pm	Tools for Data Collection	Dr P. D. Pore				
	1.00 - 1.45 pm	Lunch Break					
:55 →3Q3	1.45 - 3.15 pm	Role of statistics in Research Methodology: -Sampling techniques, sample size estimation, power analysis.  Preparation of master chart, Data types & writing,  Proposed statistical analysis in the protocol	Mr. Rupesh Deshmukh				
25-781:00	3.15 – 3.45 pm	Literature search	Dr. Shivkumar Iyyer				
	3.45 – 4.15 pm	References	Dr. Medha Puranik				
	4.15 – 4.45 pm	Writing research protocol with focus on methodology	Dr. N. S. Mani				
	4.45 – 5.00 pm	Self-Guided Work	All facilitators				

### BHARATI VIDYAPEETH (DTU) MEDICAL COLLEGE, PUNE

### Department of Community Medicine & Medical Education Unit

### Research Methodology Workshop Report

15/09/2020

Sub: Research Methodology Workshop (RM WS) for PG Students (JR I)

Batch 1: 17<sup>th</sup> August 2020 Batch 2: 18<sup>th</sup> August 2020 Batch 3: 08<sup>th</sup> September 2020

Department of Community Medicine and Medical Education Unit of Bharati Vidyapeeth (DTU) Medical College, Pune conducted the annual Research Methodology Workshop for newly enrolled Post Graduate students(JR I). This year instead of two days, the workshop was conducted for one day due to COVID. The one day lecture series were conducted in 3 batches on 17<sup>th</sup>, 18<sup>th</sup> August and 08<sup>th</sup> September 2020.

Total 124 PG students (including MD/MS, super specialty, and MSc students) participated in the workshop. 1 faculty observer attended the workshop with batch 1.

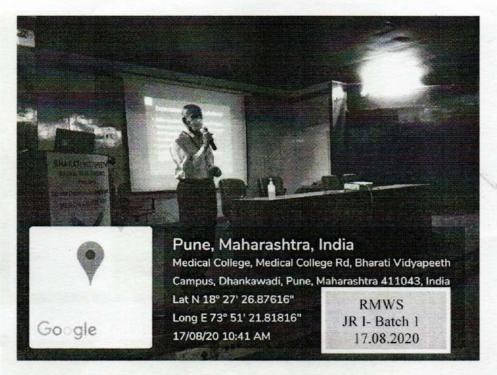
The sessions on both days began on time and went as per schedule. Students from all the batches reported on time and participated actively in the sessions. The participants first introduced themselves and their thesis topic. Compared to previous batches many students had not finalized the topic due to COVID duties leading to less time at disposal. During each session, the speaker explained their topic with examples relating to participants research topic. All the aspects of research right from formulation of research question and title, the study designs, the statistical aspects like estimating sample size etc. were covered in detail. Literature search and writing references were also dealt with hands on. The various guidelines and ethical issues pertaining to research were also covered.

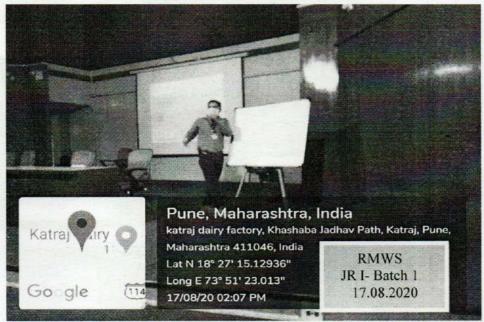
Most students had queries regarding study design and sample size estimation. Faculty discussed this with individual students during the self-guided work session. In addition, they were told to approach the Community Medicine faculty and statisticians after the workshop for guidance on these queries. Formats for documents (Consent form, Participant / Patient information sheet etc.) relevant for synopsis submission to Institutional Ethics Committee were shared with all the students on the whatsapp groups created for the workshop.

Verbal and online feedback was taken from all 3 batches after the last session. The responses in the feedback showed that all the sessions were relevant to their research, there was good & excellent use of teaching aids, the pace of the lecture was appropriate, the length of sessions was appropriate. The students appreciated the efforts to ensure that topic is understood along with good interactivity and clarification of doubts. Students found sessions on statistics, literature search, study designs and references extremely beneficial. The overall response was that the workshop is very informative; they got an orientation to the research protocol, were encouraged to apply it to their research topic.

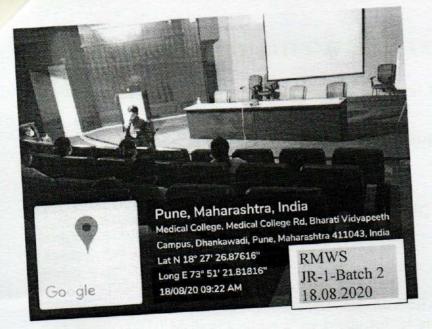
However, during the literature search session internet connectivity problem occurred. Also 4 students could not attend as they tested positive for COVID. A mop up round will be conducted or ppt will be shared with them.

Dr. Lalna Takale Coordinator RMWS 2020 Professor & Head Dept. of Community Medicine

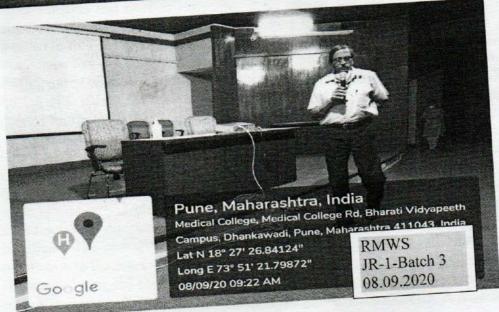












#### File No. EC/19/000196



# Government of India Directorate General of Health Services Central Drugs Standard Control Organization (Ethics Committee Registration Division)

FDA Bhawan, Kotla Road, New Delhi - 110002, India Dated: 16-Sep-2019

To

The Chairman
Institutional Ethics Committee BVDU
Bharati Hospital and Research Centre
Bharati Hospital, Pune - Satara Road Dhankawadi
PUNE Pune Maharashtra - 411043 India

Subject: Ethics Committee Re-Registration No. ECR/313/Inst/MH/2013/RR-19 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/3304 dated 04-May-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/313/Inst/MH/2013/RR-19. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

V G

Digitally signed by V G SOMANI
DIX.1-4%, C-LITTAL DIRUGS STANDAND
DIX.1-4%, C-LITTAL DIX

(Dr. V.G. Somani) Drugs Controller General (I) & Central Licensing Authority

### Conditions of Registration

- 1. The registration is valid from 08-May-2019 to 07-May-2024, unless suspended or cancelled by the Central Licencing Authority.
- 2. This certificate is issued to you on the basis of declaration/submission made by you.
- 3. Composition of the said Ethics Committee is as per the Annexure.
- 4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
  - (i) medical scientist (preferably a pharmacologist);
  - (ii) clinician;
  - (iii) legal expert;
- (iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
  - (v) lay person.
- 5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical,

non-medical, scientific and non-scientific areas with at least,

- (i) one lay person;
- (ii) one woman member;
- (iii) one legal expert:
- (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.
- 6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
- 7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.
- 8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.
- 9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
- 10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
- 11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.
- 12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
- 13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any
- 14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
- 15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.
- 16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.
- 17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.
- 18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.
- 19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8: Provided that the approving Ethics Committee shall

such case be responsible for the study at the centre: Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

- 20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.
- 21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.
- 22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.
- 23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.
- 24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.
- 25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.
- 26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.
- 27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.
- 28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.
- 29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
- 30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.
- 31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.
- 32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

#### File No. - EC/NEW/INST/2020/656



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

2nd Floor, IRCS Building, New Delhi - 110001 Dated : 27-Jul-2020

### **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: Institutional Ethics Committee, Bharati Vidyapeeth Deemed To be

University Medical College, Pune Satara Road , Dhankawadi, Pune 411043.

Address: Bharati Vidyapeeth Deemed To be University Medical College, Pune,

Bharati Vidyapeeth (DTU) Medical College, PUNE, Pune, Maharashtra -

411043

Contact No: 020-24373226,238

Fax: 020-24372175

- 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 Digitally signed by ANU NAGAR NAGAR NAGAR (Anu Nagar)

Joint Secretary

Department of Health Research Designated Authority



### Government of India

Ministry of Health & Family Welfare Directorate General of Health Services Office of Drugs Controller General (India) Central Drugs Standard Control Organization

> FDA Bhawan, Kotla Road, New Delhi – 110 002, India Dated: Oldo Dolf

To

The Chairman
Institutional Ethics Committee
Bharati Vidyapeeth Deemed University Medical College
Department of Biochemistry, II<sup>nd</sup> Floor
Pune-Satara Road, Dhankawadi
Pune- 411043, Maharashtra
India

Sub:- Ethics Committee re-registration No. ECR/518/Inst/MH/2014/RR-17 issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

### Sir/Madam,

Please refer to your application submitted to this Directorate for the re-registration of Ethics Committee.

Based on the documents submitted by you, this office hereby re-registers the INSTITUTIONAL ETHICS COMMITTEE situated at BHARATI VIDYAPEETH DEEMED UNIVERSITY MEDICAL COLLEGE, DEPARTMENT OF BIOCHEMISTRY, II PLOOR, PUNE-SATARA ROAD, DHANKAWADI, PUNE- 411043, MAHARASHTRA, INDIA with Re-Registration Number ECR/518/Inst/MH/2014/RR-17 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

- 1. The re-registration shall be in force from 07.02.2017 to 06.02.2020, unless it is sooner suspended or cancelled.
- 2. This registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
- 3. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
- 4. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
- 5. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
- 6. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
- 7. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
- 8. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

### ECR/991/Bharati/Inst/MH/2013/Re-Registration-2017

- 9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.
- 10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.
- 11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
- 12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
- 13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:
  - I. Basic medical scientist (preferably one pharmacologist)
  - II. Clinician
  - III. Legal expert
  - IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
  - V. Lay person from community
- 14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.
- 15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
- 16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
- 17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
- 18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and reregistration is sought for Institutional Ethics Committee.
- 19. Funding mechanisms for the Ethics Committee to support their operations should be designed to ensure that the committees and their members have no financial incentive to approve or reject particular studies.
- 20. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
- 21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.
- 22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco-regional and community settings similar to that of the registered Ethics committee. The approving ethics committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.
- 23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (4) mentioned above.

(Dr. V.G. Somani)

Joint Drugs Controller (I) & Licensing Authority



Print

### F. No. 25/152/2012-AWD

Government of India

Ministry of Environment, Forests & Climate Change

Animal Welfare Division

O/o Committee for the Purpose of Control and Supervision of Experiments on

Animals (CPCSEA)

\*\*\*\*\*

5th Floor, Vayu Block, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi - 110003 06/12/2016

To

Dr. Vivek Saoji, Chairman

Bharati Vidyapeeth's Medical College

Bharati VidyapeethUniversity Pune, Pune-Satara Rd, Pune - 411043,

Maharashtra

Email: drviveksaoji@yahoo.co.in

Mobile: 9823064630

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)-regarding

Sir,

The registration of your establishment with CPCSEA has been renewed for a period of five years from the date of issue of this letter

- The new registration number of your establishment
  is <u>258/PO/ReBi/S/2000/CPCSEA for Research for Education</u>
   *purpose and Breeding for in-house use on small animals*. Henceforth,
   the new registration number may kindly be quoted in all your future
   correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr.Vivek Saoji	Biological Scientist, Chairperson
2	Dr. Vijaya Pandit	Scientist Incharge of Animal House Facility
		Scientist from different discipline,

3	Dr. Jayshree Dawane	Member Secretary
4	Dr.Sameer Borkar	Veterinarian
5	Dr.Manjiri Karandikar	Scientist from different discipline

 CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	Dr. Arun Baburao Gadge Pasayadan , 28/3/21 Samarth Colony , Vishalnagar, Jagtap Dairy Pimple Nilakh, Pune – 411027, Maharashtra Contact No :09881977751 Email :arungadge@gmail.com	Main Nominee
2	Dr. Chandrashekhar G. Raut National Institute of Virology, 20 A, Dr. Ambedkar Road, P. B. No. 11, Pune – 411 001, Maharashtra Contact No :09423003806 Email :cgraut@gmail.com	Link Nominee
3	Dr. Rahul C. Patil Scientist, Cell Repository, National Centre for Cell Science, NCCS Complex, University of Pune Campus, Ganeshkhind, Pune -411 007, Maharashtra Contact No :9029391755 Email :rahulpatil@nccs.res.in	Scientist from outside the Institute
4	Shri. Pravin Janardhan Patil Sr. No. 178/2, The Crest, B-4/303, Tahatani Road, Pim Pale Sandagar, Pune – 411 027, Maharashtra Contact No :094220 36853 Email :Praviny2k2001@yahoo.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.
- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

• It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.).

Yours faithfully,

(S. Gowri Shankar)

Deputy Secretary (AW) & Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.

3.4.1

# Bharati Vidyapeeth (Deemed to be University) College of Nursing, Navi Mumbai SECOND YEAR M.Sc. NURSING, 2020-2021

Institute - Dental College & Hospital, Navi Mumbai

Analysis address: - dchmumbai.urkund.bvuni@analysis.urkund.com

Submitter email: - dchmumbai.urkund@bharatividyapeeth.edu

# PLAGARISM REPORT

	Students Ivame	Froblem Statement	Specialty	Reference No Date of	Result
o Z			•	plagiarism done	
1.	Ms. Bhagyashree Deepak Jadyar	titude	Medical Surgical Nursing	(D99713920)	7 %
		regarding Prevention and Management of Coronavirus among staff nurses in selected hospital of Navi-Mumbai.		Date: 26.03.2021	
<b>?</b>	Mrs. Khirabdhi Tanayya Sahu.	A comparative study to assess the effectiveness of structured teaching programme versus	Medical Surgical Nursing	(D100258267)	% 9
		pocket reference on knowledge regarding ABG analysis among staff nurses of selected	)	Date: 31.03.2021	
+		hospitals of Navi-Mumbai.			
ri	Ms. Sisira Shamas	A study to assess the health promoting behavior among nurses from selected hospitals	Medical Surgical Nursing	(D99713053)	% 9
		of Navi Mumbai.	)	Date: 26.03.2021	
4.	Ms. Reshma Pawar	A study to assess the effectiveness of structured teaching program on knowledge regarding	Medical Surgical	(D99714508)	% 6
		ventilator associated events among nursing students in selected colleges of Navi-Mumbai.	ρ	Date: 26.03.2021	

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(D99715149) Date: 30.03.2021	(D100146196) Date: 30.03.2021	(D100146213) Date: 30.03.2021	(D100146210) Date: 30.03.2021	(D100146208) Date: 30.03.2021
Community Health Nursing.	Community Health Nursing.	Obstetrics and Gynecological Nursing	Obstetrics and Gynaecological Nursing	Mental Health Nursing
A comparative study to assess the knowledge regarding common illness among mothers of under five children in selected urban and rural area of Navi-Mumbai with a view to develop an information booklet	A descriptive study to assess the knowledge regarding severe acute malnutrition (SAM) among mothers of 6 months-5 year children in selected rural area of Raigad district with a view to develop a handbook.	A study to assess effectiveness of structured teaching programme on knowledge regarding oral health among primigravidae in selected hospitals of Navi Mumbai	A study to assess the knowledge regarding Premenstrual Syndrome among adolescent girls in selected junior colleges of Navi Mumbai in a view to develop an information booklet.	A study to assess the myths and misconceptions regarding mental illnesses among adults of urban community at Navi-Mumbai in a view to develop an information booklet.
Ms. Rekha Kumbhar	Ms. Neha Purohit	Ms. Kavita Mulye	Ms. Akshata. K. Poojari	Ms. Venisa Remedies
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### Sources included in the report

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W	URL: https://www.ijsr.net/archive/v9i2/SR20207133649.pdf Fetched: 6/6/2020 6:50:17 PM	1
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Bharati Vidyapeeth

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Navi Mumbai - 400 614

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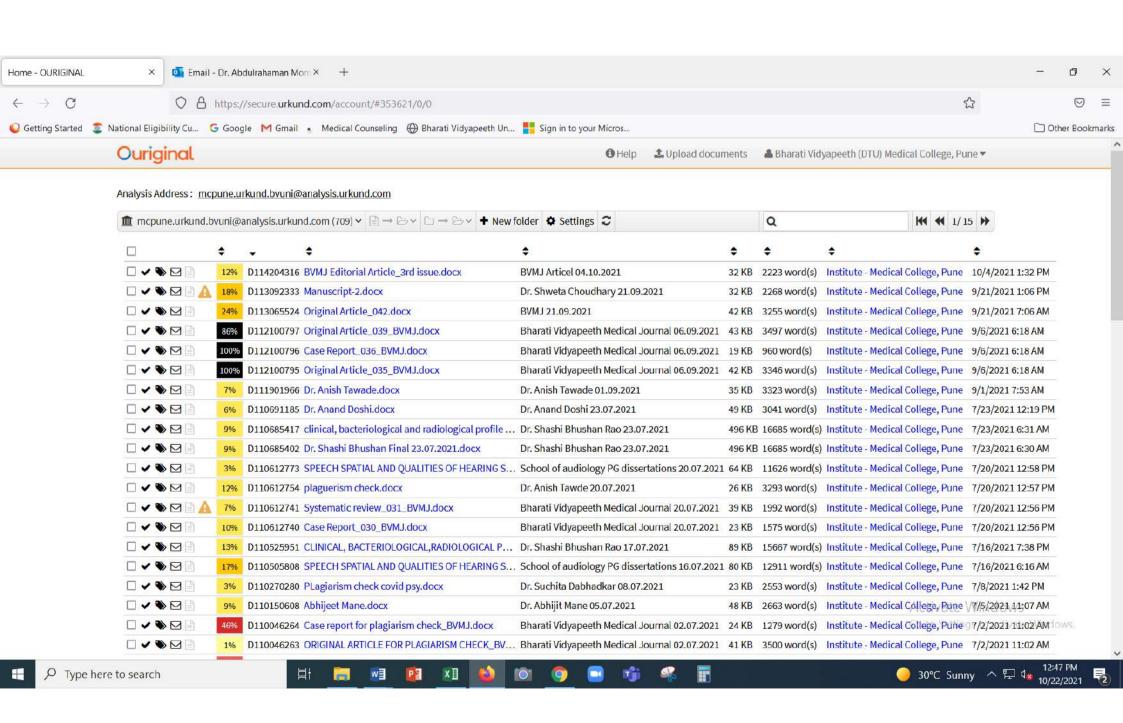
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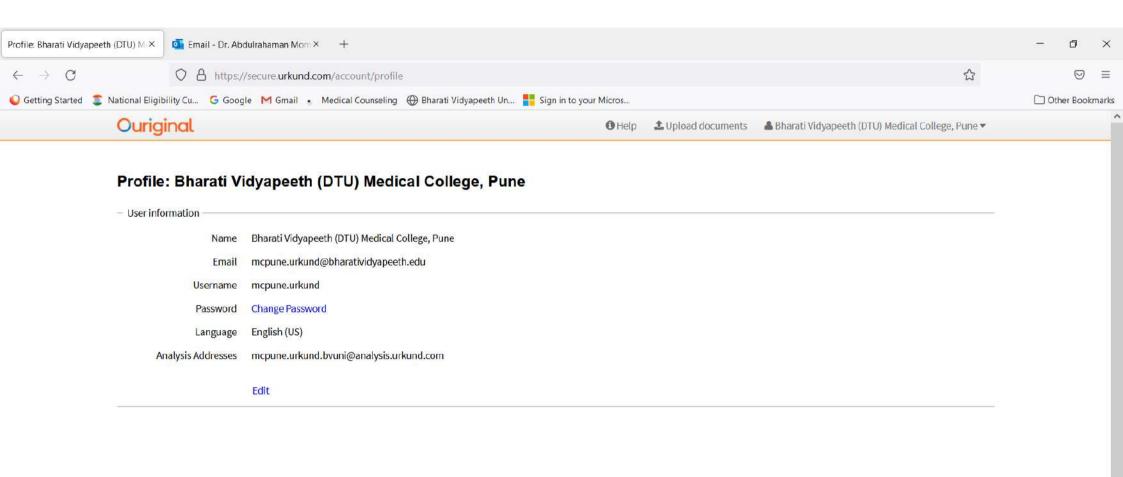
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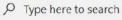
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Prof. Dr. M. M. Salunkhe M.Sc., Ph.D., F.R.S.C. Vice Chancellor

# Bharati Vidyapeeth

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Pune, India.

Founder Chancellor : Dr. Patangrao Kadam MEDICAL COLLEGE, PUNE

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BHARATI VIDYAPEETH

Dr. Vishwajeet Kadam B.Tech., M.B.A., Ph.D. Pro Vice Chancellor

Brig. (Retd) Dr. N. S. Mani M.D. (Pathology)

**Principal** 

Date: 14/07/2021

Ref. No.: BVDU/MC/L195 21-22

To.

Dr. Abdulrahaman Momin, Assistant Professor Biochemistry, Bharati Vidyapeeth Deemed to be University Medical College, Pune.

I am happy to appoint you as Chairperson of Plagiarism check and online dissertation submission committee of our college for a period of 2 years from 1.7.2021. You have been a senior faculty of our college and have contributed to the growth and development of this institute.

I am sure you will take up this responsibility and work towards attainment of goal of the committee and our institute.

I request you to convene a meeting of members of your committee, deliberate on important issues pertaining to your portfolio and submit the reports to the college office and the IQAC/NAAC Cell as and when required. A list of members is attached reverse.

A line of acceptance to the undersigned will be appreciated.

Sincerely,

Principal & Chairperson

NSNJW-

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Medical College

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Plagiarism check and online dissertation submission committee

Name		Designation	Department
Dr. Abdulrahaman Momin	Chairperson	Assistant Professor	Biochemistry
Dr. Kavita Deshpande	Member	Assistant Professor	FMT

# Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

# **Standard Operating Procedures (SOP)**

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## Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

#### **Introduction:**

The Scientific Review Committee (SRC) plays a vital role in protocol review to ensure that clinical trials are scientifically sound and that approved trials maintain patient accrual goals and scientific progress.

The Scientific Review Committee (SRC) ensures that the scientific question being asked within a protocol is relevant and that the design of the protocol is appropriate to answer that question.

## **Authority under which SRC is constituted:**

Bharati Vidyapeeth (Deemed to be University) Medical College, Pune constituted the Scientific Review Committee at Bharati Vidyapeeth (Deemed to be University) Medical College Hospital and Research Centre. The Committee will ensure that the research projects are scientifically relevant, use appropriate methodology and address safety concerns appropriately.

### **Preparation and Revision of SOP:**

The SOP for the Scientific Review Committee at Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, is prepared by Member secretary & 1-2 SRC members. The SOP draft is reviewed by all the SRC members, approved & signed by the Chairperson. The SOP is valid for period of three years from the effective date or till the next amendment, whichever is earlier. The SOP version will be updated every three yearly and amendment will be done for any interim revision/s.

### **Purpose:**

The purpose of this SOP is to contribute to the effective functioning of the Scientific Review Committee at Bharati Vidyapeeth (Deemed to be University) Medical College, Pune so that a competent and consistent scientific review mechanism, in an objective manner, is put in place for all health and biomedical research proposals dealt by the committee in accordance with National regulations, New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), CDSCO guidelines and Good Clinical Practices, International Conference/ Council on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practices, National Ethical Guidelines for Biomedical and Health Research Involving Children 2017, National Guidelines for Ethics committee reviewing Biomedical and Health Research -

Version 3.0 Amendment 01 Dated 11 Aug 2021

## Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

During Covid-19 Pandemic – ICMR April 2020, and Newer rules & regulations/ GSR as applicable.

### 1. Composition of SRC:

#### i. Membership:

The Principal of Bharati Vidyapeeth (Deemed to be University) Medical College shall appoint the Chairperson, Member Secretary and the members for the Scientific Review Committee, BVDUMC, Pune.

The Professors and Associate Professors of various faculties of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune would be appointed on the committee.

There will be 9 members in the committee. The list of the members is attached as an Annexure I.

#### ii. Tenure of Member:

The tenure of the membership will be 2 years. Each member can have a membership of maximum two tenures.

All SRC members are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies. All members shall have to sign the 'COI and Confidentiality Agreement'.

#### iii. Replacement, Resignation and Removal Procedure:

- If a member completes his or her tenure, the member secretary will inform and request the Principal to appoint a new member in his or her place.
- If a member does not wish to continue, he/she should give in writing to secretary regarding the same.
- If a member does not wish to continue and opts to leave before the completion of his or her tenure, the member secretary will inform and request the Principal to appoint a new member his or her place.

## Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

#### 2. Functions of SRC:

- Chairperson shall head the committee; preside over its meeting and conduct the meeting according to Good Clinical Practice (GCP). If he/she is unable to attend the meeting, he/she will nominate an SRC member to preside over the meeting and conduct it. In case of long absence of the chairperson, the Chairperson in consultation with member secretary will nominate another member for performing his/her functions during his absence. The Acting Chairperson will have all the powers of the Chairperson for that meeting.
- The previous Chairperson will continue till the appointment of new Chairperson.
- Member Secretary shall be responsible for administrative work of the committee.
- Minimum quorum of five is required for conducting a meeting. All the members shall have equal voting rights. The research projects will be approved by open voting system.

More than 50% votes are required to approve the project. In case of even number of votes with a tie, the chairperson will have decisive vote to take the decision.

## 3. Submission of Research Proposal:

The research proposal for approval by the committee shall be submitted to the **Secretariat Office** at the following address:

#### **Scientific Review Committee Office:**

4<sup>th</sup> floor, Bharati Hospital & Research Centre Pune-Satara Road, Dhankawadi Pune-411043 Phone No- 020 40555555, Ext 2265

Eight copies of the dossier containing following documents should be submitted to SRC for scientific review:

- **a.** Covering letter addressed to the SRC Chairperson
- **b.** Study Protocol should include the following points (as applicable):
  - i. Study title
  - ii. Study Objectives Primary & Secondary
  - iii. Study Endpoints-Primary & Secondary
  - iv. Study Rationale

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- v. Investigational product, Comparator product & Indication
- vi. Study population
- vii. Duration of the study
- viii. Number of Centres
  - ix. Study design
  - x. Inclusion Criteria
  - xi. Exclusion Criteria
- xii. Methodology
- xiii. Consort Chart
- xiv. Statistical Analysis
- c. Case Report Form
- **d.** Investigator's Brochure (if applicable)
- e. Principal Investigator's Curriculum Vitae
- **f.** Study Proforma (if applicable)

### 4. Processing of Proposals:

Member Secretary/secretariat shall circulate hard & /or soft copies of the research proposals to the members so as to reach them at least two weeks before the proposed date of the SRC meeting. If a proposal requires urgent review, the documents may be sent few days prior to meeting.

#### 5. Review meeting:

- i. Member Secretary shall convene a meeting of the committee in consultation with the Chairperson every 2-3 monthly or after receiving 2 (two) proposals. If more than two proposals are received, next meeting can be convened after 2 weeks.
- ii. If a proposal requires urgent review a special meeting may be convened in consultation with the chairperson where justified.
- iii. Member Secretary shall inform date, day, time and venue of the meeting to all the members and the Principal Investigator (PI), whose proposal is being discussed and request him/her to be available for presentation of project.

If the PI is not able attend the meeting, he/she should depute the authorized person / Co-Investigator for the same with advance intimation.

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- iv. SRC shall discuss the study in detail with special attention to scientific contents of the study.
- v. Required quorum of minimum 5 members should be present for the meeting.
- vi. A member will not participate in the deliberations of the project in which she / he has a Conflict Of Interest (COI).
- vii. The Chairperson is the concluding authority in SRC voting or final decisions, he/she will sign the minutes of SRC meeting. The SRC will issue the letter to the PI with its final recommendation as (1) Approval, (2) Conditional Approval subject to clarifications/acceptable revision, or (3) Rejection. Recommendations will be based on consensus. The letters to respective PI shall be signed and issued by the Member Secretary. In case secretary is part of PI's team, the letters shall be issued by the Chairperson.
- viii. If some clarifications from PI are required, then PI will send clarifications to the Chairperson. The Chairperson will go through that and will take the decision of approval or discuss it in next meeting. If required, Chairperson can appoint subcommittee of 2 3 members and the decision will be taken by this subcommittee.
- ix. The decision of each proposal shall be documented and communicated to the PI in writing within 10 working days after the meeting.
- x. Member Secretary shall maintain the attendance log of each meeting.
- xi. Once the proposal is approved by the SRC, it can be forwarded to Institutional Ethics Committee for review and approval, further amendments of the study documents will be reviewed and approved by the IEC.
- xii. One copy of the project submitted to SRC will be archived and the extra copies of SRC submission will be destroyed after SRC meeting maintaining its confidentiality.

All the dissents and rejection of proposals shall be recorded as part of minutes.

#### 6. Expert advisors

Scientific Review Committee (SRC) shall appoint an expert advisor when felt necessary who may be invited to attend the meeting and advise the Committee on a subject related to his/ her

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specialty and thus help committee in making decision. He/ she shall not vote on the proposal but his/her opinion will be recorded. The fact that an expert advisor was oppointed will be documented in the minutes & letter to the PI.

#### 7. Appeal on rejection

If SRC rejects the proposal, the PI may appeal for the reconsideration within 12 weeks for a fresh review after providing the justifications of such consideration.

## 8. Record keeping / Administration:

The Member Secretary shall maintain the correspondence pertaining to the SRC. The office will maintain all the records pertaining to the functioning of the SRC such as:

- a. The current list of the SRC members and their CVs
- b. The current version of the SOP
- c. Meeting related documents for e.g. Minutes of Meeting (MOM), attendance etc.
- d. Correspondence between the SRC and the PI /study team and other relevant records will be retained for a minimum period of three years.

#### 9. Revision History:

This SOP version 3.0 Amendment 01 Dated 11 Aug 2021 supersedes the previous version 3.0 dated 14 Oct 2019 addendum 01 dated 03 Apr 2020.

The amendments are as follows:

- i. The number of SRC members is changed from 8 to 9.
- ii. The tenure of SRC membership is changed from 3 years to 2 years
- iii. In the section, 2. Functions of SRC it is added that, 'The previous Chairperson will continue till the appointment of new Chairperson'.
- iv. In the section, Purpose New guidelines are added.

This SOP is effective from 11 Aug 2021. Its duration is three years from the effective date or till the next amendment, whichever is earlier.

The SOP of the SRC may be made available to any member from Bharati Vidyapeeth (Deemed To Be University) upon a written / oral request for the same to the SRC.

Version 3.0 Amendment 01 Dated 11 Aug 2021

# Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

## **Annexure I**

## Format for Scientific Review Committee member list

Sr. No. Name	Affiliation	Role in the SRC
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# Bharati Vidyapeeth (Deemed to be University) Medical College, Pune

# ADDENDUM 01 TO SRC SOP Version 3.0 - Dated 14 Oct 2019 Date: 03 Apr 2020

This addendum is added to SRC SOP due to current COVID -19 pandemic situation in Maharashtra and India. This addendum is intended to clarify regarding the procedure for expedited review and approval of the projects submitted to SRC and also to conduct online/ web meeting.

SRC may be called for review of clinical trial proposal which requires expedited approval by SRC. In such cases the documents may be circulated to members of Scientific Review Committee and IEC simultaneously. Review and approval may be obtained from SRC members by mail or through online/ web meeting.

## Online/ Web meeting:

In emergency situations like pandemics, disease outbreaks or disasters, lock-down etc. when SRC meeting in person is not possible, online/ web meeting may be held to review the projects. The documents of the meeting will be circulated via mail to all SRC members prior to the meeting. Records of the meeting shall be maintained. The minutes of meeting will be prepared on this basis. The decision regarding the projects discussed during the meeting shall be communicated to respective PI.

Chairperson

11 Aug 2021

Scientific Review Committee Bharati Vidyapeeth University Medical College



# Bharati Vidyapeeth

(Deemed to be University)

# Medical College, Pune, India

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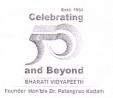
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Pune - 411 043.

Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No.: BVDU/MC/423/18-19

Date: 19/5 /20/8

To,

Dr. Shubha Nagpal Professor in Ophthalmology Bharati Vidyapeeth (Deemed to be University) Medical College Pune

## Sub: Nomination of Dr Shubha Nagpal as a Chairperson of Scientific Review Committee

Dear Dr. Nagpal,

I am pleased to inform you that you have been nominated as the Chairperson of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11<sup>th</sup> May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

Sincerely

Bharati Vidyapeeth

(Deemed to be University) Medical College

Pune - 42

Website: www.mcpune.bharatividyapeeth.edu Email: mcpune@bharatividyapeeth.edu

# BHARATI VIDYAPEETH DEEMED UNIVERSITY MEDICAL COLLEGE PUNE 43

Ref. No.BVDUMC/DOO / 23 /2018-19

Date: 22/05/2018

From,

Dr.Shubha Nagpal Prof & Head

Department of Ophthalmology,

BVDUMC, Pune -43

To,

The Principal

BVDUMC, Pune 43

# Subject: Nomination as Chairperson of Scientific Review Committee

Dear Sir,

Reference your letter No. BVDU/MC/4231/18-19 Dated 19/05/2018.

I am grateful for being appointed to the post of Chairman of the Scientific Review Committee of BVDUMC, Pune and thankfully accept the same.

with regards

Dr. Shubha Nagpal

Prof & Head

Department of Ophthalmology,

BVDUMC, Pune -43



Clerk RM Committee

Date: 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

Sub: Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Shubha Nagpal

Professor

Department of Ophthalmology

Bharati Vidyapeeth (Deemed to be University) Medical College,



Prof. Dr. Shivajirao Kadam M.Sc., Ph.D.

Chancellor

Prof. Dr. M. M. Salunkhe M.Sc., Ph.D., F.R.S.C.

Vice Chancellor

Ref. No.: BVDU/MC/86/2019-2020

# Bharati Vidyapeeth

(Deemed to be University)
Pune, India.

Founder Chancellor: Dr. Patangrao Kadam MEDICAL COLLEGE, PUNE

★ Accredited with 'A<sup>+</sup> Grade (2017) by NAAC ★
★ Category-I University Status by UGC ★

★ NIRF Ranking - 62 ★

"Social Transformation Through Dynamic Education"



Dr. Vishwajeet Kadam B.Tech., M.B.A., Ph.D. Pro Vice Chancellor

Brig. (Retd) Dr. N. S. Mani M.D. (Pathology)

Principal

Date: 12/05/2020

To,

Dr. Ruma Deshpande
Associate Professor
Department of Pediatrics
Bharati Vidyapeeth (Deemed to be University) Medical College,
Pune

Sub: Nomination of Dr. Ruma Deshpande as a Member/ Member Secretary of Scientific Review Committee

Dear Dr. Deshpande,

I am pleased to inform you that you have been nominated as the Member/ Member Secretary of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from May 2020 which may be renewed.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

NS Nam'

Principal

PRINCIPAL Bharati Vidyapeeth

(Deemed to be University)

Medical College Pune - 411 043. **Date:** 18 May 2020

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

Sub: Consent for being Member/ Member Secretary of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member/ Member Secretary of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Ruma Deshpande Associate Professor

Department of Pediatrics

Bharati Vidyapeeth (Deemed to be University) Medical College,



Prof. Dr. Shivajirao Kadam M.Sc., Ph.D. Chancellor

Prof. Dr. M. M. Salunkhe M.Sc., Ph.D., F.R.S.C Vice Chancellor

# Bharati Vidyapeeth

(Deemed to be University) Pune, India.

# Founder Chancellor: Dr. Patangrao Kadam **MEDICAL COLLEGE, PUNE**

★ Accredited with 'A+' Grade (2017) by NAAC ★ ★ Category-I University Status by UGC ★ ★ NIRF Ranking - 62 ★

"Social Transformation Through Dynamic Education"



Dr. Vishwajeet Kadam B.Tech., M.B.A., Ph.D. **Pro Vice Chancellor** 

Brig. (Retd) Dr. N. S. Mani

Principal

Date: 28/11/2020

Ref. No.: BVDU / MC /2775/20.21

Dr. Mahadevan Kumar

Professor

Department of Microbiology

Bharati Vidyapeeth (Deemed to be University) Medical College,

Sub: Nomination of Dr. Mahadevan Kumar as a Member of Scientific Review Committee

Dear Dr. M Kumar,

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 27th November 2020 which may be renewed.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), CDSCO guidelines, GCP and ICMR guidelines while reviewing the Research proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

N/SNQu-

Sincerely

Bharati Vidyapeeth (Deemed to be University) Medical College,

Pune-43

PRINCIPAL Bharati Vidyapeeth

(Deemed To Be-University) Medical College

Pune-43

Received

**Date:** 30 Nov 2020

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Mahadevan Kumar

**Professor** 

Department of Microbiology

Bharati Vidyapeeth (Deemed to be University) Medical College,



# **Bharati Vidyapeeth**

(Deemed to be University)

# Medical College, Pune, India

Accredited with 'A+' Grade (2017) by NAAC 'A' Grade University Status by MHRD, Govt. of India Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC

FOUNDER-CHANCELLOR: Hon'ble Dr. PATANGRAO KADAM

M.A., LL.B., Ph.D.

PRINCIPAL:

BRIG.(RETD) DR. N. S. MANI

M.D. (Pathology)





Pune-Satara Road.

Pune - 411 043.

Mojum

Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No.: BVDU/MC/422 18-19

Date: 19/5/2018

To.

Dr. Shivakumar Iyer Professor in Critical Care Medicine Bharati Vidyapeeth (Deemed to be University) Medical College Pune

## Sub: Nomination of Dr. Shivakumar Iyer as a Member of Scientific Review Committee

Dear Dr.Iyer,

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11<sup>th</sup> May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

Sincerely

Bharati Vidyapeeth (Deemed to be University)

Medical College Pune - 43

Website: www.mcpune.bharatividyapeeth.edu

Email: mcpune@bharatividyapeeth.edu

Date: 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Shivakumar(I)er

**Professor** 

Department of Critical Care Medicine

Bharati Vidyapeeth (Deemed To Be University) Medical College,



# **Bharati Vidyapeeth**

(Deemed to be University)

# Medical College, Pune, India

Accredited with 'A+' Grade (2017) by NAAC 'A' Grade University Status by MHRD, Govt, of India Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC

FOUNDER-CHANCELLOR:

Hon'ble Dr. PATANGRAO KADAM

M.A., LL.B., Ph.D.

PRINCIPAL:

BRIG.(RETD) DR. N. S. MANI

M.D. (Pathology)





Pune-Satara Road,

Pune - 411 043. Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No.: BVDU/MC/420/18-19

Date: 19 / 5 /20/8

To,

Dr. Jayshree Dawane Associate Professor in Pharmacology Bharati Vidyapeeth (Deemed to be University) Medical College

# Sub: Nomination of Dr. Jayshree Dawane as a Member of Scientific Review Committee

Dear Dr. Dawane,

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11th May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

Sincerely

NSNOw-

Principal Bharati Vidyapeeth

(Deemed to be University)

Medical College Pune - 42

> Website: www.mcpune.bharatividyapeeth.edu Email: mcpune@bharatividyapeeth.edu

Date: 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Jayshree Dawane

Associate Professor

Bharati Vidyapeeth (Deemed To Be University) Medical College



# **Bharati Vidyapeeth**

(Deemed to be University)

# Medical College, Pune, India

Accredited with 'A+' Grade (2017) by NAAC 'A' Grade University Status by MHRD, Govt. of India Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC

FOUNDER-CHANCELLOR: Hon'ble Dr. PATANGRAO KADAM

M.A., LL.B., Ph.D.

PRINCIPAL:

BRIG.(RETD) DR. N. S. MANI

M.D. (Pathology)





Pune-Satara Road,

Pune - 411 043.

Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No.: BVDU/MC/419/18-19

Date: 19/5/2018

To.

Dr. Salil Barsode Associate Professor in Obstetrics & Gynecology Bharati Vidyapeeth (Deemed to be University) Medical College

# Sub: Nomination of Dr. Salil Barsode as a Member of Scientific Review Committee

Dear Dr. Barsode.

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11th May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards.

Sincerely

Bharati Vidyapeeth

(Deemed to be University)

Medical College.

Pune - 42

Website: www.mcpune.bharatividyapeeth.edu

Email: mcpune@bharatividyapeeth.edu

**Date:** 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Salil Barsode Associate Professor

Department of Gynecology & Obstetrics

Bharati Vidyapeeth (Deemed to be University) Medical College,



# Bharati Vidyapeeth

(Deemed to be University)

# Medical College, Pune, India

Accredited with 'A+' Grade (2017) by NAAC
'A' Grade University Status by MHRD, Govt. of India
Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC

FOUNDER-CHANCELLOR:
Hon'ble Dr. PATANGRAO KADAM

M.A., LL.B., Ph.D.

PRINCIPAL:

BRIG.(RETD) DR. N. S. MANI

M.D. (Pathology)





Pune-Satara Road,

Pune - 411 043.

Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No. : BVDU/MC/421 | 18-19

Date: 19 15 120/8

To,

Dr. Manjiri Datar Associate Professor in Psychiatry Bharati Vidyapeeth (Deemed to be University) Medical College Pune

## Sub: Nomination of Dr. Manjiri Datar as a Member of Scientific Review Committee

Dear Dr. Datar,

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11th May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

न ने द्वाडीया

With Regards,

NSNOW

Sincerely

PRINCIPAL

Bharati Vidyapeeth (Deemed to be University)

Medical College Pune - 42

Website: www.mcpune.bharatividyapeeth.edu
Email: mcpune@bharatividyapeeth.edu

Date: 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Manjiri Datar Associate Professor

Department of Psychiatry,

Bharati Vidyapeeth (Deemed To Be University) Medical College,



# **Bharati Vidyapeeth**

(Deemed to be University)

# Medical College, Pune, India

Accredited with 'A+' Grade (2017) by NAAC 'A' Grade University Status by MHRD, Govt. of India Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC

FOUNDER-CHANCELLOR:
Hon'ble Dr. PATANGRAO KADAM

M.A., LL.B., Ph.D.

PRINCIPAL:

BRIG.(RETD) DR. N. S. MANI

M.D. (Pathology)





Pune-Satara Road,

Pune - 411 043.

Phone: 020-24373226, 24364561

Fax No: 020-24372175

Ref. No.: BVDU/MC/424/18-19

Date: 19 / 5 /20 18

To,

Dr. Narula Arvinder Pal Singh Associate Professor in Community Medicine Bharati Vidyapeeth (Deemed to be University) Medical College Pune

Sub: Nomination of Dr. Narula Arvinder Pal Singh as a Member of Scientific Review Committee

Dear Dr. Narula,

I am pleased to inform you that you have been nominated as the Member of the Scientific Review Committee of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

Your tenure shall be for a period of three years with effect from 11th May 2018.

As a member of Scientific Review Committee you will review all the research proposals that may be put up by the faculty and students of Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

It is expected that the Scientific Review Committee meeting be held once in every three months and more frequently if required.

You are also expected to follow the Schedule Y, CDSCO guidelines, GCP & ICMR guidelines while reviewing the Research Proposals.

I hope that you will accept this responsibility. I request you to communicate your acceptance as soon as possible.

With Regards,

NSNQu-

Sincerely

Bharati Vidyapeeth
(Deemed to me University)

Medical College Pune - 43

> Website: www.mcpune.bharatividyapeeth.edu Email: mcpune@bharatividyapeeth.edu

Mrs. Ashwini Bapat Peadiatrics dept. Date: 22 May 2018

To,

The Principal

Bharati Vidyapeeth (Deemed To Be University) Medical College

Pune

**Sub:** Consent for being Member of 'Scientific Review Committee (SRC), Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

Respected Sir,

I thank you for nominating me as a Member of the 'Scientific Review Committee of Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune'. I willingly give you my consent for the same.

Thanking you,

Dr. Narula Arvinder Pal Singh

Associate Professor

Department of Community Medicine

Bharati Vidyapeeth (Deemed to be University) Medical College,

# Scientific Review Committee Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

SRC/2020/46

## Minutes of the 67th SRC Meeting

The 67<sup>th</sup> meeting of Scientific Review Committee (SRC) Bharati Vidyapeeth (Deemed to Be University) Medical College, Pune was held online on Thursday, 10 Dec 2020 at 02.30 pm.

The members who attended the meeting were:

Dr. Shubha Nagpal (Chairperson)

Dr. Ruma Deshpande (Member Secretary)

Dr. Shivakumar Iyer

Dr. Jayshree Dawane

Dr. Narula Arvinder Pal Singh

Dr. Salil Barsode

Dr. Manjiri Datar and Dr. Mahadevan Kumar were unable to attend the meeting and had intimated about the same.

Required quorum was present for the meeting.

## Agenda for this meeting was as follows:

- 1. Confirmation of minutes of 66<sup>th</sup> SRC meeting held on 26 Nov 2020
- 2. Review of two new projects
- Dr. Ruma Deshpande read out the salient points from the minutes of the last i.e. 66<sup>th</sup> SRC meeting. Minutes of the 66<sup>th</sup> SRC meeting, held on 26 Nov 2020, were unanimously approved by all the members.

## I. Discussion on new projects:

1. **Protocol Title:** A validation study of Artificial Intelligence-based Software for prediction of fetal distress

The above project was submitted by Dr. Girija Wagh, Principal Investigator, Professor, Department of Obstetrics and Gynaecology, Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Pune

PI, Dr. Girija Wagh explained the study and made a power point presentation.

## Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

## Discussion on the project:

The SRC reviewed and discussed the project thoroughly in the meeting.

- a) Dr. Nagpal asked how much is the sample size and at how many centers this study will be conducted.
- PI informed that the sample size is 2000 and study will be conducted at one centre i.e Department of Gynecology and Obstretics, Bharati Hospital and Research Centre, Pune
- b) Dr. Nagpal asked whether entire data will collected at Pune Center only.
- PI informed that the entire data, collected will be sent to Bangalore centre.
- c) Dr. Nagpal asked would you intervene according to the results of the study.
- PI informed that this is an observational study and only data will be captured. The clinical intervention will continue as per the departmental protocol.
- d) Dr. Nagpal asked whether consent of the patient will be taken as the data will be shared?
- PI said yes, the consent of the patient will be taken.
- e) Dr. Narula asked about the cost of equipment Daksh?
- PI informed that Daksh is an app and it is free of cost. It is already being used in Government set up.
- f) Dr. Dawane asked how many deliveries per month occur in our hospital.
- PI informed that 110 to 150 deliveries occur in our hospital.

After reviewing all the study documents, Scientific Review Committee, Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune grants **Approval** for the conduct of the above referred study, subject to final approval by 'Institutional Ethics Committee, BVDU'.

 Protocol Title: Efficacy and Safety of Ferric Carboxymaltose Injection in Iron deficiency anemia in Pregnancy: A Prospective Observational Study.
 Protocol No.: Protocol No.: FCM 2020/01 Version 01 dated 17/10/2020

The above project was submitted by Dr. Girija Wagh, Principal Investigator, Professor, Department of Obstetrics and Gynaecology, Bharati Vidyapeeth (Deemed to be University)

Medical College and Hospital, Pune

PI, Dr. Girija Wagh explained the study and made a power point presentation.

Discussion on the project:

The SRC reviewed and discussed the project thoroughly in the meeting.

# Scientific Review Committee Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

- a) Dr. Dawane asked about the hypersensitivity reaction due to Ferric Carboxymaltose (FCM) injection and whether sensitivity test needs to be done.
- PI, Dr. Wagh informed that hypersensitivity reaction is less due to FCM and sensitivity test is not required.
- b) Dr. Ruma asked in the protocol, it is mentioned that Hemoglobin levels will be done at baseline, 4 weeks and 6 weeks. If it is low, then whether again repeat dose would be given to the participant?
- PI informed that repeat dose will be given to the participant.
- Dr. Nagpal mentioned that in the protocol it is written that "The maximum single dose should not exceed 1,000 mg iron in first week. If according to Ganzoni's formula patient calculated dose would be more than 1000 mg then patient will be called on next week on day 7 for rest of the dose. Maximum cumulative dose should not give more than 1500mg". According to this repeat dose cannot be given.
- Dr. Barsode added that if Hemoglobin does not increase at 4 weeks, PI can wait for few weeks and check Hemoglobin at 6 weeks.
- SRC asked if Hemoglobin is low at 6 weeks, then what would be the further course of action.
- c) Dr. Ruma said that in the protocol in the section, 11. Study Design, Procedure & duration, it is mentioned that 'This is a prospective, non-interventional, post-marketing, observational, investigator initiated study.....' She mentioned that it is an interventional study not non-interventional one.
- PI agreed with the same and said that she will do this change in the protocol.
- d) Dr. Ruma said that Primary objective of the study is, 'To assess the efficacy of ferric carboxymaltose (FCM) injection in moderate to severe iron deficiency anemia in pregnancy'. She asked whether both moderate and severe iron deficiency anemia cases will be included in the study.
- PI informed that only moderate iron deficiency anemia cases i.e. hemoglobin (Hb) level more than 7 and less than 10 g/dl will be included in the study.
- Dr. Ruma mentioned that in the Protocol one of the inclusion criteria mentions as, 'Pregnant women with hemoglobin (Hb) level more than 6 and less than 10 g/dl'.
- PI informed that she will change in the protocol & make it 7.
- e) Dr. Nagpal asked whether DCGI has given permission for the use of FCM in pregnancy
- PI informed that she will find out and inform SRC.

After reviewing all the study documents, Scientific Review Committee, Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune grants Conditional Approval for the above referred study.

# Scientific Review Committee Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune

SRC seeks clarifications for the following:

- a) As per protocol, Hemoglobin levels will be done at baseline, 4 weeks and 6 weeks. If it is low then what would be the further course of action.
- b) At the site, moderate iron deficiency anemia cases i.e. hemoglobin (Hb) level more than 7 and less than 10 g/dl will be included in the study. But in the Protocol one of the inclusion criteria mentions as, 'Pregnant women with hemoglobin (Hb) level more than 6 and less than 10 g/dl'.

Please make necessary changes in the protocol.

c) In the protocol in the section, 11. Study Design, Procedure & duration, it is mentioned that 'This is a prospective, non-interventional, post-marketing, observational, investigator initiated study.....' But this is an interventional study not non-interventional one.

Please make necessary changes in the protocol.

- d) Please clarify whether DCGI has given permission for the use of FCM in pregnancy.
- 3. **Protocol Title:** An Open-label observational study to evaluate the success rate of natural micronized progesterone for the prevention of pregnancy induced hypertension

PI, Dr. Girija Wagh informed that the above referred project was submitted for SRC review and approval but this project is cancelled, so she did not present this project.

Meeting ended with vote of thanks.

Dr. Shubha Nagpal

Chairperson

Chairperson
Scientific Review Committee
Bharati Vidyapeeth University Medical College