Major Achievements

Achievements	Page no
ISO Certification	1-2
Center of Excellence for Laparoscopy surgery by Storz, Karl Storz endoscope.	3-4
Atal Ranking of Institutions on Innovation Achievement (ARIIA) 2021	5-6
Four Star Certificate of Institution's Innovation Council (IIC) for the Academic Year 2020-21	7-8
NABH Accredited Hospitals (NM and ABD)	9-13
NABL Accredited laboratories (NM and ABD)	14-17
SIRO Accredited Research Laboratory (NM)	18-19
NIRF 2020 (University Rank Band 151-200)	20-21
American Heart Association	22-24
Institutional Animal Ethics Committee (IAEC)	25-27
Ethics Committee Registration Division, MGM Medical College and Hospital, Aurangabad	28-32
Ethics Committee Registration Division, MGM Institute of Health Sciences, Navi Mumbai	33-41
Zonal Transplantation Coordination Center, Aurangabad	42-54
ICMR	55-58
Adverse Drug Reactions Monitoring Centre (AMC)	59-60

ISO Certification

UQSR. Certificate

MGM Institute of Health Sciences

MGM Educational Campus, Sector 1, Kamothe, Kalamboli, Navi Mumbai, Maharashtra- 410209, India

And hereby declares that the organization is in conformance with:

ISO 14001: 2015

For the following scope of activities:

Education Institute and Hospital Courses

Further clarification regarding the scope of this certificate and the applicability of Environmental Management standard requirements (Energy Audit/ Green Audit) may be obtained by contacting the organization

Certificate No. UQSR-1450-MIHS

Current Issue Date: 07 th Oct.	Original Issue Date: 07 th Oct. 2019	Issue No. 01	IAF Code: 37
2019 Expiry Date: 07 th Sep. 2020	Recertification Date: 07th Sep. 2022*		

* Validity of certificate is subjected to the continued satisfactory performance during surveillance audit



UQSR Global Private Limited

Formerly known as

Universal Quality Standards Registrar www.uqsr.org

For information concerning validity of certificate, you can visit the site: www.uqsnorg

This document is property of UQSR and should be returned on request. Any unauthorised alteration, forgery or fabrication of the content or appearance of this document is unlawful and offendors may be prosecuted to the fullest extent of the law.





Center of Excellence for Laparoscopy surgery by Storz, Karl Storz endoscope.



Shaping the Future of Endoscopy with you



KARL STORZ Endoscopy India Private Ltd. • 28, Barakhamba Road • New Delhi-110 001

The Dean MGM Medical College Aurangabad Date : 21.01.2021

Dear Sir,

M/s KARL STORZ SE & CO. KG., GERMANY is a pioneer and world leader in Laparoscopy equipment and instruments. We are also a leading brand in India and provide the latest high-class equipment for laparoscopic surgery. We are actively involved and are at the forefront in training and up-gradation of the skills of practicing surgeons and residents across the country.

The Department of Surgery, MGM Medical College and Hospital, Aurangabad is performing high-quality Advanced Laparoscopic and Endoscopic surgeries. We appreciate MGM's vision to pass on the benefits of ultramodern treatment facilities that are provided to the poorest of poor at a negligible cost.

We also admire the efforts taken by Dr. Pravin Suryawanshi, Professor & Head, Department of Surgery to propagate the art and skills of Laparoscopic Surgery amongst his surgical colleagues and residents. His academic and research contribution to the development of Laparoscopy is praiseworthy.

In appreciation of the quality of services and academic contribution by MGM's Department of Surgery KARL STORZ India Pvt. Ltd. takes great honour in recognizing your Centre as a "Centre of Excellence for Laparoscopy Surgery".

To further improve the quality of services and the teaching and learning experience for the junior surgeons, we are happy to install our World-class High-End product at your premises. We have installed OR1, OT lights and AIDA (Advance Image Data Archiving System) worth more than Rs.60,00,000/- and other equipment at a very subsidized cost at your esteemed institution.

We are sure with this latest upgradation of the ultra-modern operation theatre will benefit many junior surgeons to be trained further for better patient outcome.

Looking forward to this long association for the development of laparoscopy as a sub-specialty.

Thanking you, Praveen Singla **Business Manager** - MAS

Corporate & Registered Office: KARL STORZ Endoscopy India Private Ltd. 11th Floor, Dr. Gopal Das Bhawan 28, Barakhamba Road New Delhi-110 001 / India

ħ

12

2

Phone: +91 1143 7430 00 Toll free: 1800 1234 698 Fax: +91 11 4374 3010 E-Mail: corporate@karlstorz.in Branch Office: B-100, Ground Floor Naraina Industrial Area, Phase-1 New Delhi-110 028 / India Fax: +91 11 2509 6866

CIN No.: U33119DL1998PTC092006 www.karlstorz.com Atal Ranking of Institutions on Innovation Achievement (ARIIA) 2021



INNOVATION CELL

(Government of India)



Ministry of Education

(Government of India)





Certificate of Recognition

This is to certify that

MGM INSTITUTE OF HEALTH SCIENCES, NAVI MUMBAI

is recognised in the band "PROMISING" under the category "University & Deemed to be University (Private/Self Financed) (Technical)" in Atal Ranking of Institutions on Innovation Achievement(ARIIA) 2021, a flagship program of the Ministry of Education, Government of India.

29th December 2021.

SADELNA

Dr. Anil D Sahasrabudhe Chairman, AICTE

14, N

Shri K Sanjay Murthy Secretary (HE), MoE

Abhay Jere

Dr. Abhay Jere Chief Innovation Officer MoE's Innovation Cell

Four Star Certificate of Institution's Innovation Council (IIC) for the Academic Year 2020-21













CERTIFICATE

Institution's Innovation Council (IIC) established at

MGM Institute of Health Sciences, Navi Mumbai

had undertaken various activities prescribed by Innovation Cell, Ministry of Education, Govt. of India to promote Innovation and Start-up in campus during the IIC calendar year 2020-21.

SADELWINS

Prof. Anil D.Sahasrabudhe Chairman AICTE

Abhay Jere

Dr. Abhay Jere Chief Innovation Officer MOE, Innovation Cell

Mr. Dipan Sahu Assistant Innovation Director MOE, Innovation Cell

Certificate No: 2167

Issued On : 2022-01-03

NABH MGM Medical College & Hospital, Navi Mumbai

National Accreditation Board for Hospitals & Healthcare Providers

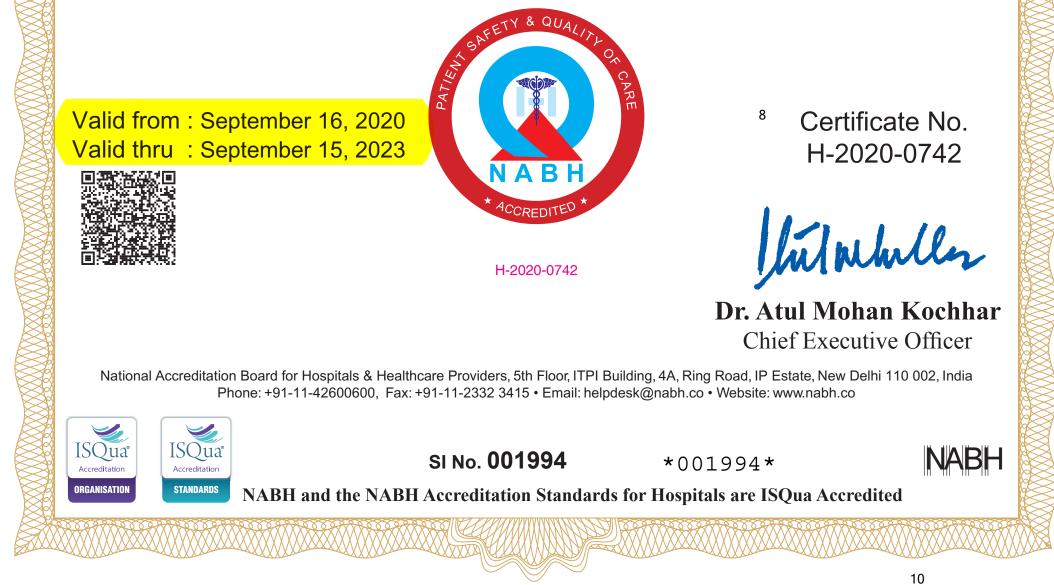
(Constituent Board of Quality Council of India)

CERTIFICATE OF ACCREDITATION

MGM Medical College & Hospital

Sector1, Plot 1 &2, Kamothe, Navi Mumbai Raigarh - 410209, Maharashtra

has been assessed and found to comply with NABH Accreditation Standards for Hospitals. This certificate is valid for the Scope as specified in the annexure subject to continued compliance with the accreditation requirements.





NABH MGM Medical College & Hospital, Aurangabad

National Accreditation Board for Hospitals & Healthcare Providers

(Constituent Board of Quality Council of India)

Certificate of Accreditation

MGM Medical College Hospital and Medical Center Research Institute (MCRI) Central Naka Road, N-6, CIDCO Aurangabad - 431003, Maharashtra

has been assessed and found to comply with NABH Accreditation Standards for Hospitals. This certificate is valid for the Scope as specified in the annexure subject to continued compliance with the accreditation requirements.

Valid from : September 16, 2018 Valid thru : September 15, 2021



Certificate No. H-2018-0573

Dr. Harish Nadkarni Chief Executive Officer

National Accreditation Board for Hospitals & Healthcare Providers, 5th Floor, ITPI Building, 4A, Ring Road, IP Estate, New Delhi 110 002, India Phone: +91-11-42600600, Fax: +91-11-2332 3415 • Email: helpdesk@nabh.co • Website: www.nabh.co



ISQUA Accreditation STANDANDS

NABH and the NABH Accreditation Standards for Hospitals are ISQua Accredited



National Accreditation Board for Hospitals & Healthcare Providers

(Constituent Board of Quality Council of India)

NABH/H-2016-1090/L-01/2022/2810

March 28, 2022

To, Dr Rajendra Bohra DEAN MGM Medical College Hospital and Medical Center Research Institute Aurangabad Mobile: 9225304660 E-mail: mgmmcha@themgmgroup.com

Sub.: Extension of Accreditation of MGM Medical College Hospital and Medical Center Research Institute, Aurangabad

Dear Dr Rajendra Bohra,

This has reference to the request for continuation of your status as an accredited organization after the expiry of your accreditation on 15-09-2021.

We have noted from our records that a renewal assessment is conducted on $26^{th}\,27^{th}\,\&\,28^{th}$ November 2021.

Keeping in view the current constraints owing to the Covid-19 pandemic, NABH has decided to provide extension of validity of accreditation till June 30, 2022 or till the decision on the renewal application is taken by the accreditation committee, whichever is earlier.

Please ensure the HCO has cleared all due fee payment.

Thanking you,

Sincerely yours,

Inchaller

(Dr. Atul Mohan Kochhar) CEO-NABH

NABL MGM Medical College & Hospital, Aurangabad



National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

MGM'S CENTRAL PATHOLOGY LABORATORY, MAHATMA GANDHI MISSION HOSPITAL

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

N-6, CIDCO, AURANGABAD, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number: MC-2839

Issue Date:

29/06/2021

Valid Until:

28/06/2023

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL. (To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity: MAHATMA GANDHI MISSION HOSPITAL

Signed for and on behalf of NABL



N. Venkateswaran Chief Executive Officer

NABL MGM Medical College & Hospital, Navi Mumbai



National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

PLOT NO 1 AND 2, NH4 JUNCTION, SION, PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number:

MC-2166

Issue Date:

26/04/2019

Valid Until:

25/04/2021*

*The validity is extended for one year up to 25.04.2022

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL. (To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : Mahatama Gandhi Mission

Signed for and on behalf of NABL



N. Venkateswaran Chief Executive Officer

Scientific and Industrial Research Organisations (SIROs)



द्रमाष/TEL : 26962819, 26567373 (EPABX)

: 26565694, 26562133 : 26565687, 26562144 : 26562134, 26562122 फैक्स/FAX : 26960629, 26529745 : http:/www.dsir.gov.in



भारत सरकार विज्ञान और प्रौद्योगिकी मंत्रालय वैज्ञानिक और औद्योगिक अन्संघान विभाग टेक्नोलॉजी भवन, नया महरोली मार्ग, नई दिल्ली - 110016

GOVERNMENT OF INDIA MINISTRY OF SCIENCE AND TECHNOLOGY Department of Scientific and Industrial Research Technology Bhavan, New Mehrauli Road, New Delhi - 110016



Date: 23rd April, 2020

The Vice Chancellor **MGM Institute of Health Sciences** (Deemed to be University) Sector - 1, Kamothe, Navi Mumbai - 410 209 Maharashtra

Recognition of Scientific and Industrial Research Organisations (SIROs). Subject :

Dear Sir.

This has reference to your application for recognition of MGM Institute of Health Sciences (Deemed to be University), Kamothe, Navi Mumbai, Maharashtra as a Scientific and Industrial Research Organisation (SIRO) by the Department of Scientific and Industrial Research under the Scheme on Recognition of Scientific and Industrial Research Organisations (SIROs), 1988.

This is to inform you that it has been decided to accord recognition to MGM Institute 2. of Health Sciences (Deemed to be University), Kamothe, Navi Mumbai, Maharashtra from 27.03.2020 to 31.03.2022. The recognition is subject to terms and conditions mentioned overleaf_

Receipt of this letter may kindly be acknowledged. 3.

Yours faithfully,

Responde

(Dr. S.K. Deshpande) Scientist - 'G'

NIRF Overall (Rank-band 151-200)

🌡 Gallery | 🚠 Contact



National Institutional Ranking Framework Ministry of Education

Gov

vernment	of	India	

HOME	ABOUT NIRF	PARAMETERS	DOCUMENTS	RANKING	NOTIFICATION/ADVT	FAQS CONTACT
		India Ra	nkings 2020:	Overall (Rar	ik-band: 151-200)	
			Institution list	in alphabetical or	ler	Ba
		Nam	e		City	State
Amity Univ	versity				Gurugram, Haryan	na Haryana
Amity Univ	versity				Jaipur	Rajasthan
Annamalai	i University				Annamalainagar	Tamil Nadu
Anurag Gro	oup of Institutions				Hyderabad	Telangana
Avinashilin	igam Institute for Hom	e Science & Higher Edu	cation for Women		Coimbatore	Tamil Nadu
Babasheb	Bhimrao Ambedkar Ur	liversity			Lucknow	Uttar Pradesh
Coimbator	e Institute of Technolo	gу			Coimbatore	Tamil Nadu
Dharmsinh	n Desai University				Nadiad	Gujarat
English & F	Foreign Languages Univ	versity			Hyderabad	Telangana
Governme	nt College of Technolog	бу			Coimbatore	Tamil Nadu
Indraprast	ha Institute of Informa	tion Technology Delhi			New Delhi	Delhi
Jawaharl	lal Nehru Technologica	l University			Anantapur	Andhra Pradesh
Jaypee Ir	nstitute of Information	Technology			Noida	Uttar Pradesh
Jaypee U	Jniversity of Information	n Technology			Solan	Himachal Pradesh
JSS Scien	nce and Technology Uni	iversity			Mysuru	Karnataka
KLE Tech	nnological University				Dharwad	Karnataka
Konasee	ema Institute of Medica	Sciences Research Fou	indation		Amalapuram	Andhra Pradesh
Kuruksh	etra University				Kurukshetra	Haryana
M. G. R.	Educational and Resea	rch Institute			Chennai	Tamil Nadu
Maharaj	ia Sayajirao University o	of Baroda			Vadodara	Gujarat
Manipur	r University				Imphal	Manipur
Mepco S	Schlenk Engineering Col	lege			Sivakasi	Tamil Nadu
MGM Ins	stitute of Health Science	es			Navi Mumbai	Maharashtra
ΝМАМ	I Institute of Technolog	у			Nitte, Udupi	Karnataka
Nagalan	d University				Zunheboto	Nagaland
National	l Institute of Technolog	y Hamirpur			Hamirpur	Himachal Pradesh
National	l Institute of Technolog	y Patna			Patna	Bihar
Nirma U	Iniversity				Ahmedabad	Gujarat
DESCO	llege of Engineering				Mandva	Karnataka

American Heart Association



American Heart Association.

International Training Agreement

Company Information:

International Training Center ("ITC"):	Mahatma Gandhi Mission Medical College and Hospital
Address:	MGM Medical College and Hospital, Plot No. 01 Sector 01 Kamothe, Navi Mumbai, Maharashtra 410209, India
	Not for Profit / University

This Agreement is between the American Heart Association, Inc. ("AHA"), a New York not-for-profit corporation, having its principal offices at 7272 Greenville Avenue, Dallas, Texas 75231-4596, and ITC. IN CONSIDERATION of the mutual promises contained herein, the parties agree as follows:

1. Term: Beginning Date: January 24, 2020. Ending Date: January 24, 2023. This Agreement will be in effect for a period of Three (3) calendar years. It may be renewed for additional one (1) year periods by letter issued from AHA.

2. AHA ECC Courses to be Taught by ITC:

Basic Life Support	Advanced Cardiac Life Support
Provider Course(s)	Provider Course(s)
Instructor Course(s)	Instructor Course(s)

3. Geographic Territory: India

4. Insurance: \$28,024.69 US

ITC will obtain and maintain at its expense, commencing upon the beginning date of this Agreement and during its entire term, liability insurance from a qualified insurance carrier, as set out above. This policy will specify that it may not be modified or canceled by the insurer, except after thirty (30) days prior written notice by the insurer. Upon execution of this Agreement ITC will provide the AHA with a certificate of insurance showing the required coverage.

5. Copyrights: ITC acknowledges and agrees that the AHA owns all copyrights in the ECC Materials, and ITC may not copy, or permit others to copy, distribute, perform or make derivative works based upon the ECC Materials, Course Completion Cards, or eCards.

6. Marks: ITC acknowledges the AHA's trademark rights and ownership of the name "American Heart Association", the heart-and-torch trademark and slogans (e.g., "Life is Why") (hereinafter "AHA Marks"). ITC will not use or display the AHA Marks. ITC shall not apply for any trademark registrations with respect to any AHA Marks or any marks similar to the AHA Marks.

7. Entire Agreement: This Agreement, including the terms and conditions set out on Page Two, contains the entire agreement between the parties relating to the rights granted and the obligations assumed.

EXECUTED by the parties on the date(s) set out below.

American Heart Association, Inc.	Interna
Signature: Kate E Jam	Signatu
Name: Keith Jansen	Name:
Title: SVP, International	Title:
Date: January 24, 2020	Date:

			()
Interna	tional Training C	ente	r
Signatu	re:	2	Sic
Name:	GURUNATH	s	NARSHETT
Title:	DEAN		
Date:	18-02-	205	20

Emergency Cardiovascular Care International Programs - 7272 Greenville Avenue, Dallas, Texas 75231-4596 Form Date: Nevember 9: 2015

MGM SKILLS LAB DATE: 25/0/1200 (a) "Program Guidelines" means the current Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Program Administration Manual: Guidelines for Program Administration and Training (hereinafter "PAM"), and AHA Instructor's Manuals, as they may be amended and/or supplemented by the AHA from time to time.

(b) "Course Completion Cards" or "Cards" are defined as documents made available or provided by AHA, and which indicate a student's successful completion of a specified Course.

(c) "Course" or "Courses" are defined as those courses that follow the curricula of the AHA and teach emergency cardiovascular care according to the Program Guidelines.

(d) "ECC Materials" are defined as emergency cardiovascular care textbooks and materials published by the AHA.

(e) "eCards" means those electronic records that Training Centers may distribute to, or provide access to, students pursuant to Program Guidelines to indicate that the student participated in or successfully completed a Course.

(f) "Instructors" are individuals who have successfully completed AHA authorized Provider and Instructor training and who are authorized by ITC to teach Provider courses to other individuals.

(g) "Training Sites" are organizations engaged or authorized by ITC to teach Courses under the auspices of ITC.

9. ITC Role and Responsibilities:

(a) ITC will teach Courses only within the Geographic Territory, and agrees to do so in compliance with the Program Guidelines. (b) ITC may contract with other entities (hereinafter "Training Sites") who agree to teach Courses under the direction and guidance of ITC. ITC assumes full responsibility for the actions and performance of the Training Sites, and will ensure that Training Sites teach in compliance with the Program Guidelines.

(c) Periodically, as requested by the AHA, ITC will provide the AHA with a current and accurate list of Training Sites, Instructors, the number of students taught, and such other information as may be requested by AHA but only to the extent allowed by local law and the terms of any applicable consent, if required.

(d) ITC will insure that each student has individual possession of an authorized Course-specific textbook before, during, and after training.

(e) ITC will be responsible for the issuance and security of Course Completion Cards and eCards as outlined in the Program Guidelines: (i) ITC will establish a system for ensuring that Cards are issued only to authorized Training Sites. (ii) ITC and its authorized Training Sites will only issue the appropriate course-specific Course Completion Card or eCard to each student who successfully completes the applicable Course.

(f) ITC will obtain any and all required licenses, permits or documentation and is solely responsible for compliance with all laws and regulations applicable to training activities conducted under this Agreement. ITC will obtain any required or appropriate consent from each student before sharing that student's name and Course completion information with the AHA through AHA's online systems (which systems may include data storage outside of ITC's Territory).

10. Relationship of Parties:

The parties acknowledge and agree that each is an independent entity and, as such, neither party may represent itself as an employee, agent, or representative of the other; nor may it incur any

MGM SKILLS LAB DATE: 28 10/ 200 obligations on behalf of the other party. 11. Termination:

(a) The Agreement may be terminated by either party, without cause, upon sixty (60) calendar days' prior written notice.

(b) Either party may terminate this Agreement if the other party breaches any term or condition of this Agreement and fails to cure the breach within thirty (30) calendar days after receipt of written notice by the non-defaulting party. The following will also constitute breach or default under this Agreement: (i) Failure to exist or operate as a legal entity or to maintain an office address; or (ii) Assignment for the benefit of creditors, becoming generally insolvent, a party of a petition for bankruptcy or for entity reorganization under any bankruptcy act or similar statute.

(c) The AHA may terminate this Agreement upon written notice if it determines, in its sole discretion, that any of the activities permitted or contemplated under this Agreement pose a significant legal or business risk to the AHA.

(d) Notwithstanding anything to the contrary in this Agreement, AHA may terminate this Agreement if ITC or any Training Site conducts Courses in any country on which the United States government or other governmental entity (except those that are contrary to United States' laws), that (i) imposes sanctions that would prevent the AHA from conducting Courses either directly or indirectly in the country or (ii) for which ITC, Training Site or AHA must obtain a license from the applicable government to conduct Courses. If the United States government should impose sanctions on any country named in the Geographic Territory, the AHA at its option may (i) immediately terminate this Agreement as to that country in which event ITC and its Training Sites will immediately cease conducting Courses in the country, or (ii) may immediately terminate this Agreement in its entirety upon written notice to ITC.

(e) ITC will not distribute any AHA Course Completion Cards or eCards or designate itself, in any manner or any place, as an authorized ECC training center of AHA after this Agreement has been terminated or expired. In addition to any remedies by law or in equity available to AHA, ITC will pay the AHA Two Hundred Dollars (200 US\$) as a penalty for each Course Completion Card issued after termination or expiration of this Agreement. Upon termination or expiration of this Agreement, AHA shall have no liability or obligations to ITC, and ITC shall retain no rights under this Agreement.

12. Warranties:

(a) ITC warrants and represents to the AHA that as of the effective date and at all times during the term of this Agreement: (i) ITC, its agents, affiliates, members, representatives, distributors, contractors, and Training Sites will be in compliance with this Agreement, the provisions of the U.S. Foreign Corrupt Practices Act and all applicable U.S., local, state and federal laws and regulations, and applicable laws or regulations of any jurisdictions whose laws may apply; (ii) ITC is not a tobacco company, or a tobacco company corporate subsidiary or parent, nor does it receive revenue from tobacco products. "Subsidiary" and "parent" are defined as an entity in which there exists a direct or indirect Five Per Cent (5%) or greater ownership interest by a tobacco company.

(b) EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE.

13. Indemnification and Liability:

(a) ITC will indemnify, defend and hold harmless



the AHA and its directors, officers, employees, distributors, agents. members. volunteers successors and assigns from and against all suits. proceedings, actions, demands, claims, losses, liability, damages or expenses (including reasonable attorneys' fees and legal costs) arising from (i) ITC's performance or breach of its obligations under this Agreement, (ii) ITC's operation activities and/or distribution of Course Completions Cards, (iii) any breach or alleged breach of ITC's representations or warranties, (iv) any act or omission of ITC in any country in the Geographic Territory, and (v) any act or omission of Training Sites, Instructors, ITC's affiliates, agents, partners or representatives,

(b) The AHA will not be liable for any indirect, special, consequential or incidental damages, including lost profits or any other kind of damages, even if it has been warned of the possibility of such loss or damage. In no event will the AHA's liability under this Agreement exceed \$1,000 (US\$).

14. Force Majeure: Neither party will be in default under this Agreement, if such results, whether directly or indirectly, from fire, explosion, strike, freight embargo, vis major, or of the public enemy, war, terrorism, civil disturbance, act of any government, de jure or de facto, or agency or official thereof, labor shortage, transportation contingencies, unusually severe weather, default of manufacturer or a supplier, quarantine restrictions, epidemic, or catastrophe.

15. Notices: Any notice required or permitted under this Agreement, will be given in writing and will be deemed to have been duly given upon actual receipt if delivered personally or by courier with receipt obtained therefrom to the parties at their respective addresses.

16. Miscellaneous Provisions:

(a) This Agreement may not be assigned by ITC without the AHA's prior written consent.

(b) No amendment of this Agreement will be binding or enforceable on either party hereto unless in writing signed by both parties.

(c) Should any part, term, or provision of this Agreement be declared to be invalid, void, or unenforceable by a court of competent jurisdiction, all remaining parts, terms, and provisions hereof will remain in full force and effect, and will in no way be invalidated, impaired or affected thereby.

(d) This Agreement will be governed by the laws of the State of New York without regard to its conflict of laws provisions. Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in Dallas, Texas in accordance with the International Arbitration Rules of the American Arbitration Association. The language of the arbitration will be English. The arbitrators will have no authority to award punitive damages, and may not, in any event, make any ruling, finding, or award that does not conform to the terms and conditions of this Agreement. Judgment upon any award rendered through arbitration may be entered in any court having jurisdiction. Injunctive relief may be sought in anv court of competent jurisdiction. (e) This agreement contains the entire agreement

between the parties and supersedes all prior written and oral communications. This Agreement will be written in and governed by the English language.

(f) AHA reserves the right to appoint other ITCs within the Geographic Territory.

(g) The following paragraphs and their subparagraphs will survive termination of this Agreement: 13 (Indemnification and Liability), 16(d) and 16(e)

DIRECTOR MGM SKILLS LAB DATE: 25 1011 2020

Institutional Animal Ethics Committee (IAEC)



14 Carl 4 1 1 1 1 1

प्रशुओं पर परीक्षण के नियंत्रण एवं चर्यवेक्षण के प्रयोजनार्थ समिति (सीपीसीएसईए) Government of Tudia

पर्यावरण, वन एवं जलवाय परिवर्तन मंत्रालय

भारत 'सरकार 🐘 🐘

Ministry of Environment, Forest and Climate Change Animal Welfare Division Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)

F. No. 25/127/2010-AWD

02/05/2018

То

Dr. Savita Shahani, Chairperson IAEC, Mahatma Gandhi Mission's Medical College, Sector - 18, Kamothe, Navi Mumbai - 410209, Maharashtra, Mobile: 9819277578 E-mail: <u>drshahanirediffmail@yahoo.co.in</u>

Subject: Revision of Institutional Animals Ethics Committee (IAEC) - regarding

Madam,

Kindly refer to your application on the above subject. CPCSEA hereby accords approval to your request for revision of IAEC.

2. Accordingly, the revised LAEC is as under:

S.No.	Name of IAEC Members Designation in IAEC			
1.	Dr. Savita Shahani	Biological Scientist (Chairperson)		
2.	Dr. Ipseeta Ray	Scientist from different biological discipline(Member Secretary)		
3.	Dr. R S Inamdar	Scientist from different biological discipline		
4.	Dr. G S Narshetty	Scientist Incharge of Animal House Facility		
.5.	Dr. Mohan Latkar	Veterinarian		
6.	Dr. Uddhav Kalu Chaudhari	Main Nominëe		
7.	Dr. Vikas D. Dighe	Link Nommee		
8.	Dr. Dhanjit Kumar Das	Scientist from outside the Institute		
9.	Prof. Vishnu N. Thakare	Socially Aware Nominee		
		Conté		

5वां तल, वायु ब्लॉक, इंदिरा पर्यावरण भवन, जोर बाग रोड नई दिल्ली—110003 दूरभाष : 011-24695231, टेलीफेक्स : 011-24695424 ईमेल : cpcseafmet@gowin, वेबसाईट : http://cpcsea.nic.in

5th Floor, Vayu Block, Indira Paryavaran Bhawan, Ior Bagh Read, New Delhi-110003 Phone: 011-24695231, Telefax : 011-24695424, Email: cpcsca-mer@gov.mewCbsite.http://cpcsca.nie.in 3. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC mettings, 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 unavailablity in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a Calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

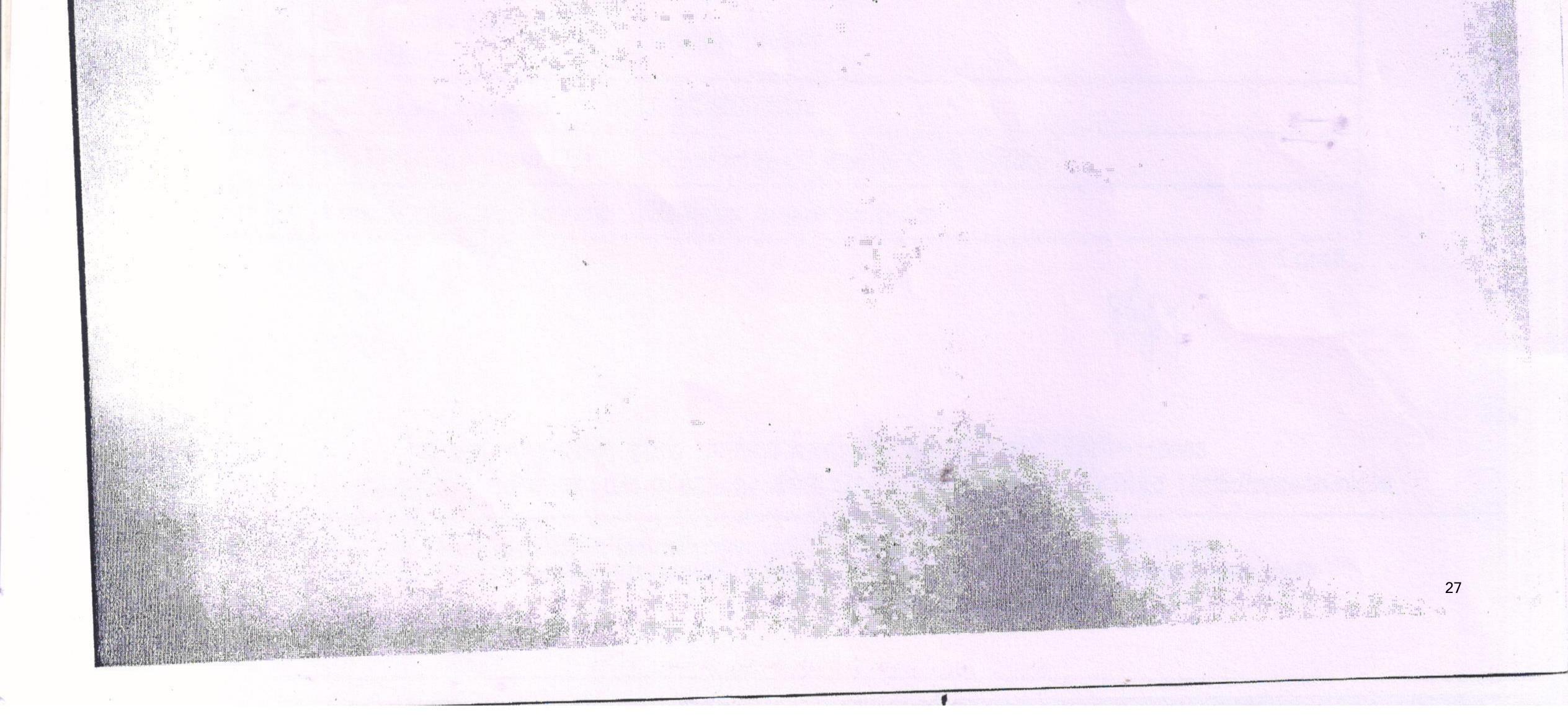
4. The above composition of IAEC is valid upto the renewed period of registration i.e. 18.01.2022.

Yours faithfully,

Under Secretary (CPCSEA)

Copy for information to Nominees of CPCSEA:

- 1. Dr. Uddhav Kalu Chaudhari- Main Nominee
- 2. Dr. Vikas D. Dighe- Link Nominee
- 3. Dr. Dhanjit Kumar Das- Scientist from outside the Institute
- 4. Prof. Vishnu N. Thakare- Socially Aware Nominee



Ethics Committee Registration Division MGM Medical College And Hospital, Aurangabad

File No. EC/20/000329



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: 07-Oct-2020

То

The Chairman MGM ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECT MGM Medical College And Hospital N-6, CIDCO Aurangabad Aurangabad Maharashtra - 431003 India

Subject: Ethics Committee Re-Registration No. ECR/581/Inst/MH/2014/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2020/9615 dated 09-Sep-2020 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/581/Inst/MH/2014/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

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

Conditions of Registration

1. The registration is valid from 11-Sep-2020 to 10-Sep-2025, 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, nonmedical, 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 nongovernmental 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

from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in 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/20/000329



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: 07-Oct-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. Abhaysinh K Bhosle	LLB (Master of Laws (LL.M.))	Legal Expert
2	Dr. Shafat Husain Talib	MBBS (MD - General Medicine)	Clinician
3	Dr. Lakshmi Nagabhushanam Rachakonda	MBBS (MD - Obstetrics & Gynaecology)	Clinician
4	Dr. Gautam Ajit Shroff	MBBS (MD/MS - Anatomy)	Basic Medical Scientist
5	Dr. Manvendra Sawalaram Kachole	BSc (M.Sc)	Chair Person
6	Dr. Jyoti Anil Bobde	MBBS (MD)	Member Secretary
7	Dr. Suparna Milind Bindu	MBBS (MD Pathology)	Basic Medical Scientist
8	Dr. Sarath Babu Venkatesan	BPT (Ph.D)	Scientific Member
9	Dr. S M Mahajan	MBBS (MD-Epidemiologist)	Clinician
10	Ms. Kanwaljeet Kaur	BSc (MSc-Nursing)	Scientific Member
11	Mr. Sanjay Sewalikar	B. COM (MSW-Master in Social Work)	Social Scientist
12	Mr. Mangesh V Shinde	B.Ed (M.Ed)	Lay Person

WAY, GOVEN

(Dr. V.G. Somani) Drugs Controller General (I) & Central Licensing Authority Ethics Committee Registration Division MGM Institute of Health Sciences, Navi Mumbai

File No. EC/19/000510



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: 20-Mar-2020

То

The Chairman Ethics Committee for Research on Human Subjects MGM Institute of Health Sciences Sector -1 Kamothe Navi Mumbai Raigad Maharashtra -410209 India

Subject: Ethics Committee Re-Registration No. ECR/457/Inst/MH/2013/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/6200 dated 30-Sep-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/457/Inst/MH/2013/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

(Dr. V.G. Somani)

Drugs Controller General (I) & Central Licensing Authority

Conditions of Registration

1. The registration is valid from 20-Mar-2020 to 19-Mar-2025, 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 nongovernmental 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/19/000510 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: 20-Mar-2020

Composition of the Ethics Committee:-

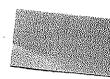
Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Shirish Joshi	MBBS (MD-Pharmacology)	Basic Medical Scientist
2	Dr. Prakash Prabhakarrao Doke	MBBS (PSM)	Clinician
3	Dr. G.S Narshetty	MBBS (MS Surgery)	Clinician
4	Dr. Alaka Deshpande	MBBS (MD Medicine)	Chair Person
5	Dr. Savita Ramesh Shahani	MBBS (MD Pharmacology)	Member Secretary
6	Dr. KARUNA RAMRAJE MALVIYA	Others (Master of Law)	Legal Expert
7	Mr. Eknath A Patil	B. COM (CA)	Lay Person
8	Mr. Jagdish Chandra Sharma	BSc (MPhil)	Social Scientist
9	Dr. Chander Prakash Puri	BSc (PhD)	Scientific Member
10	Dr. Smita Mahale	Ph.D	Scientific Member
11	Dr. Abhijit De	M.Phill, Ph.D (Cytogenetics)	Scientific Member
12	Dr. Ipseeta Ray	Ph.D	Scientific Member
13	Dr. Atmaram Bandivdekar	Ph.D	Scientific Member
14	Dr. Raman P. Yadav	Ph.D	Scientific Member

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



File No. EC/18/000006

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 - 110002, India Dated: 28-Sep-2018

То

The Chairman MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI MGM Medical College, Navi Mumbai Sector 1, Kamothe Navi Mumbai Panvel Raigad Maharashtra - 410209 India

Subject: Ethics Committee Registration No. ECR/1133/Inst/MH/2018 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2017/1645 dated 29-Jan-2018 submitted to this Directorate for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI situated at MGM Medical College, Navi Mumbai Sector 1, Kamothe Navi Mumbai Panvel Raigad Maharashtra - 410209 with Registration number ECR/1133/Inst/MH/2018 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. 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.

2. The Ethics Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the 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.

3. 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.

4. 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.

5. 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.

6. 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).

7. 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.

, 8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled. Provided that if the application for re-registration is received by the Licensing Authority within three months before the expiry, the registration shall continue to be in force until orders are passed by the said authority.

a. 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.

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 Nonscientific 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:

- Basic medical scientist (preferably one pharmacologist) 1.
- Clinician 11.
- 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

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 registration 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 locoregional 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 (3) mentioned above.

A Digitally signed by s ESWARA REDDY Date: 2018.10.04 10:26:09 (S. ESWARA Roddy) **S ESWARA** REDDY Drugs Controller General (I) & Licensing Authority

-



File No. EC/18/000006



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 - 110002, India Dated: 28-Sep-2018

То

The Chairman MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI MGM Medical College, Navi Mumbai Sector 1, Kamothe Navi Mumbai Panvel Raigad Maharashtra - 410209 India

Subject: Ethics Committee Registration No. ECR/1133/Inst/MH/2018 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

le le fart s

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2017/1645 dated 29-Jan-2018 submitted to this Directorate for the Registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No.ECR/1133/Inst/MH/2018 with the following composition and all the condition mentioned under the Registration certificate issued to you.

		- ४५ - सरवर्षन भवने	
Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Jaishree Ravindra Ghaneka	MBBS (MD - Medicine)	Clinician
2	Dr. Anant Dattatray Urhekar	MBBS (MD - Pathology & Microbiology)	Basic Medical Scientist
3	Dr. D Bhusare	MBBS (MS - General Surgery)	Clinician
4	Ms. Usha Mohite	10th (Not Applicable)	Lay Person
5 _.	Dr. Pramíla Yadav	MBBS (MD-Pharmacology)	Chair Person 🖵
6	Dr. Pradeep R Jadhav	MBBS (MD-Pharmacology)	Member Secretary
7		BSc (MSc.,PhD-Pharmacology)	
	Dr. Ravindra Shriniwas Inamdar	MBBS (MD-Physiology)	Basic Medical Scientist
9	Dr. Rajeev S Chaudhary	MBBS (MD- Forensic Medicine)	Basic Medical Scientist
10.	Ms. Rupali V Gujar	BA (MSW)	Social Scientist
11	Ms. Karuna Ramraje Malviya	LLB (LLM)	Legal Expert

SESWARA Digitally signed by SESWARA REDDY Date: 2018.10.04 REDDYEswara Reddy) 05'30' Drugs Controller General (I) & Licensing Authority

Zonal Transplantation Coordination Center, Aurangabad

[निज्ञेन घ.अ./म्.सा.वि./२म.

No. 4401



नोदणी प्रमाणपत्र

याहारे प्रमाणपत्र देण्यात येते की, खाली वर्णन केलेली सार्वजनिक विश्वरतव्यवस्था ही आज, मुंबई सार्वजनिक विश्वरतव्यवस्था अधिनियम, १९५० (सन १९५० चा मुंबई अधिनियमं २९) या Aueangabad Region, Aueangabad सार्वजनिक विश्वरतव्यवस्था नोंदणी कार्यालयात योग्य रितीने नोंदण्यात आलेली आहे. <u>Zonal Transplanto fon</u> सार्वजनिक विश्वरतव्यवस्थाचे नाव: <u>Cooscination Centee</u>, Aueangabad सार्वजनिक विश्वरतव्यवस्थांच्या नोंदणी पुरतकातील क्रमांक: <u>Dr. Sudhir Gajanan Kulkaeni</u> यांस प्रमाणपत्र दिले. आज बिनांक कि 204.2016 २०१० रोजी माइया सहीनिशी दिले.

शिक्का

महाराष्ट्र शासन सार्वजनिक आरोग्य विभाग शासन निर्णय क्रमांकः माअप्र-२०१८/प्र.क्र.२२०/आरोग्य-६ गो.ते.रुग्णालय आवार संकुल इमारत, १०वा मजला, नवीन मंत्रालय, मुंबई-०१ दिनांक: ०७ डिसेंबर, २०१८

<u>वाचा :-</u>

- 9) वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग, अधिसूचना क्र. SWP-०४१४/C.R.०८/Acts, दिनांक ३०.०६.२०१८
- २) समुचित प्राधिकारी (माअप्र) तथा संचालक, आरोग्य सेवा संचालनालय, मुंबई यांचे पत्र क्र.
 संआसे/माअप्र/लोकलऑथोकमिट/नामनिर्देशितप्रतिनिधी/७६३/२०१८,दिनांक ३०.११.२०१८

<u> प्रस्तावनाः-</u>

वैद्यकीय शिक्षण व औषधी द्रव्ये विभागाच्या संदर्भाधिन क्र. १ येथील दिनांक ३०.०६.२०१८ च्या अधिसूचनेन्वये १६ रूग्णालयांमध्ये मानवी अवयव व उत्ती प्रत्यारोपण अधिनियम, १९९४ अंतर्गत Hospital Based Authorization समिती गठीत करण्यात आलेली आहे. सदर समितीमध्ये अ.क्र.६ येथे अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग किंवा त्यांचे Nominee यांचा समितीचे सदस्य म्हणून समावेश करण्यात आला आहे. संदर्भाधिन क्र. २ येथील संचालक, आरोग्य सेवा यांचेकडून प्राप्त प्रस्तावास अनुसरून मानवी अवयव प्राधिकार समितीच्या बैठकांना उपस्थित राहण्याकरीता अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग व संचालक, आरोग्य सेवा यांचे प्रतिनिधी नामनिर्देशित करण्याची बाब शासनाच्या विचाराधीन होती.

शासन निर्णय:-

मानवी अवयव व उत्ती प्रत्यारोपण अधिनियमांतर्गत गठीत Hospital Based Authorization समितीच्या बैठकांना उपस्थित राहण्याकरीता अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग व संचालक, आरोग्य सेवा यांचे प्रतिनिधी म्हणून खालीलप्रमाणे नामनिर्देशित करण्यात येत आहे.

अ.क्र.	रूग्णालयाचे नाव	अपर मुख्य सचिव/ प्रधान सचिव/ सचिव (सा.आ.वि.) यांचे प्रतिनिधी	
٩	बॉम्बे हॉस्पीटल,मुंबई	वैद्यकीय अधिक्षक, सामान्य	सहायक संचालक, ठाणे
२	जसलोक हॉस्पीटल,मुंबई	रूग्णालय, मालवणी,	
3	पी.डी.हिंदुजा हॉस्पीटल,	मालाड, मुंबई	
	माहिम, मुंबई		
8	व्होकार्ड हॉस्पीटल,मुंबई सेंट्रल,		
	मुंबई		
ч	कोकीलाबेन धिरूभाई अंबानी		

	हॉस्पीटल, अंधेरी, मुंबई		
દ્	ग्लोबल हॉस्पीटल, परेल, मुंबई	वैद्यकीय	अतिरिक्त जिल्हा शल्य
0	फोर्टीस हॉस्पीटल, मुलुंड, मुंबई	अधिक्षक,मनोरूग्णालय,ठाणे	चिकीत्सक, जिल्हा
٢	ज्युपिटर हॉस्पीटल, ठाणे		रूग्णालय, ठाणे
9	अपोलो हॉस्पीटल, बेलापूर,	वैद्यकीय अधिक्षक, उपजिल्हा	जिल्हा शल्य चिकीत्सक,
	नवी मुंबई	रूग्णालय, पनवेल	जिल्हा रूग्णालय, ठाणे
90	आदित्य बिर्ला हॉस्पीटल,	सहायक संचालक,पुणे	जिल्हा शल्य चिकीत्सक,
	चिंचवड, पुणे		जिल्हा रूग्णालय, औंध,
99	दिनानाथ मंगेशकर हॉस्पीटल,		पुणे
	एरंडवणे, पुणे		
9२	सहयाद्री हॉस्पीटल, एरंडवणे,		
	पुणे		
93	जहांगीर हॉस्पीटल, ससून रोड,	वैद्यकीय अधिक्षक,	अतिरिक्त जिल्हा शल्य
	पुणे	मनोरूग्णालय, पुणे	चिकीत्सक, जिल्हा
98	रूबी हॉल क्लिनिक, ससून		रूग्णालय, पुणे
	रोड,पुणे		
ዓዓ	कमलनयन बजाज हॉस्पीटल,	सहायक संचालक,	जिल्हा शल्य चिकीत्सक,
	औरंगाबाद	औरंगाबाद	जिल्हा रूग्णालय,
ዓ६	एमजीएम हॉस्पीटल, औरंगाबाद		औरंगाबाद

२. सदर शासन निर्णय महाराष्ट्र शासनाच्या <u>www.maharashtra.gov.in</u> या संकेतस्थळावर उपलब्ध करण्यात आला असून त्याचा सांकेताक 201812071439599217 असा आहे. हा आदेश डिजीटल स्वाक्षरीने साक्षांकित करुन काढण्यात येत आहे.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने,

(सु.नि.गाडगे) कार्यासन अधिकारी, महाराष्ट्र शासन

प्रत,

- भा. राज्यपाल यांचे सचिव, राजभवन, मुंबई
- २) मा. मुख्यमंत्री यांचे प्रधान सचिव, मंत्रालय, मुंबई
- 3) मा.मंत्री (सार्वजनिक आरोग्य व कुटुंब कल्याण) यांचे खाजगी सचिव, मंत्रालय, मुंबई
- ४) मा. राज्यमंत्री (सार्वजनिक आरोग्य व कुटुंब कल्याण) यांचे खाजगी सचिव, मंत्रालय, मुंबई
- ५) मुख्य सचिव, महाराष्ट्र राज्य, मंत्रालय, मुंबई

- ६) प्रधान सचिव, सार्वजनिक आरोग्य विभाग, नवीन मंत्रालय, मुंबई
- ७) प्रधान सचिव, विधि व न्याय विभाग, मंत्रालय, मुंबई
- ८) सचिव, वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग, नवीन मंत्रालय,मुंबई
- ९) आयुक्त, आरोग्य सेवा तथा अभियान संचालक, राष्ट्रीय आरोग्य अभियान, मुंबई
- १०) विधि सल्लागार-नि-सहसचिव, विधि व न्याय विभाग, मंत्रालय, मुंबई
- ११) संचालक, आरोग्य सेवा, आरोग्य सेवा संचालनालय, मुंबई
- १२) संचालक, वैद्यकीय शिक्षण व संशोधन संचालनालय, मुंबई
- १३) जिल्हाधिकारी (सर्व)
- १४) सहसंचालक, आरोग्य सेवा (रूग्णालये/राज्यस्तर), आरोग्य सेवा संचालनालय,मुंबई
- १५) सहसंचालक, आरोग्य सेवा (सर्व)
- १६) उपसंचालक, आरोग्य सेवा परिमंडळे (सर्व)
- १७) सहायक संचालक (माअप्र), आरोग्य सेवा संचालनालय, मुंबई.
- १८) जिल्हा शल्यचिकित्सक (सर्व)
- १९)निवड नस्ती (आरोग्य –६)



महाराष्ट्र शासन राजपत्र

असाधारण भाग चार–अ

पुष्ठे ७, किंमत : रुपये १५.०० शनिवार, जून ३०, २०१८/आषाढ ९, शके १९४० वर्ष ४, अंक ८०]

असाधारण क्रमांक १३३

प्राधिकृत प्रकाशन

महाराष्ट्र शासनाने केंद्रीय अधिनियमांन्वये तयार केलेले

(भाग एक, एक-अ आणि एक-ल यांमध्ये प्रसिद्ध केलेले नियम व आदेश यांव्यतिरिक्त) नियम व आदेश.

MEDICAL EDUCATION AND DRUGS DEPARTMENT

New Mantralaya, 9th floor, GokuldasTejpal Hospital Complex, LokmanyaTilak Road, Mumbai 400 001, dated the 30th June 2018.

NOTIFICATION

TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994.

No. SWP-0414/C.R.08/Acts.-In exercise of the powers conferred by clause (b) of sub-section (4) of section 9 of Transplantation of Human Organs and Tissues Act, 1994 (42 of 1994) read with rules 11 and 12 of the Transplantation of Human Organs and Tissues Rules, 2014, and of all other powers enabling it in that behalf and in supersession of all earlier notifications, orders or instruments issued in this behalf, the Government of Maharashtra, hereby, constitutes, the Hospital Based Authorization Committees, for the hospital in which more than 25 transplantations have been made as specified in the Schedule appended hereto and also appoints the Chairperson and Members thereof as specified in the Schedule, for the purposes of the said Act and rules made thereunder, as follows, namely :---

Schedule

(1) Hospital Based Authorization Committee at Bombay Hospital, Marine Lines, Mumbai consisting of following Members :---

Sr. No (1)	n. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Rajkumar Patil
2	Member under clause (b) of Rule 12	Dr. Kapil Salagia
3	Member under clause (b) of Rule 12	Dr. Suresh Jain

महाराष्ट्र शासन राजपत्र असाधारण भाग चार-अ, जून ३०, २०१८/आषाढ ९, शके १९४०

२

Sr. No (1)	e. Rule (2)	Chairperson / Members (3)
4	Member under clause (c) of Rule 12	Dr. Smt. Sunita Kshirsagar.
5	Member under clause (c) of Rule 12	Dr. Vijay Punjabi
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nomineer.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(2) Hospital based Authorization Committee at Fortis Hospital, Mulund, Mumbai consisting of following Members :---

Sr. No (1)	Rule (2)	Chairperson / Members (3)
(1)	(2)	(3)
1	Chairperson under clause (a) of Rule 12	Dr. S. Narayani
2	Members under clause (b) of Rule 12	Dr. Pravin Shah
3	Members under clause (b) of Rule 12	Dr. Sandeep Gore
4	Member under clause (c) of Rule 12	Dr. Smt. Jesal Sheth
5	Member under clause (c) of Rule 12	Dr. Ramesh Punjani
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(3) Hospital based Authorization Committee at Global Hospital, Parel, Mumbai consisting of following Members :---

Sr. No (1)	. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Jigna Shortriya
2	Member under clause (b) of Rule 12	Dr. Rajiv Nikte
3	Member under clause (b) of Rule 12	Dr. Nirupa Borges
4	Member under clause (c) of Rule 12	Dr. Smt. Kajal Ahuja
5	Member under clause (c) of Rule 12	Dr. Pragji Vaja
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(4) Hospital based Authorization Committee at Jaslok Hospital, Pedar Road, Mumbai consisting of following Members :---

Sr. No (1)). Rule (2)	Chairperson / Members (3)
1 2 3 4	Chairperson under clause (<i>a</i>) of Rule 12 Member under clause (<i>b</i>) of Rule 12 Member under clause (<i>b</i>) of Rule 12 Member under clause (<i>c</i>) of Rule 12	Dr. Lalita Delima Dr. Minal Shah Dr. Ravindra Bendre Dr. Smt. Usha Shah Dr. Anil Pachnekar
5 6	Member under clause (<i>c</i>) of Rule 12 Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(5) Hospital based Authorization Committee at Kokilaben Ambani Hospital, Andheri (West), Mumbai consisting of following Members :—

Sr. No.	Rule (2)	Chairperson / Members (3)
(1)		
1	Chairperson under clause (a) of Rule 12	Dr. Ram Narayn
	Member under clause (b) of Rule 12	Dr. Jotsna Oak
		Dr. Manohar Kamat
3	Member under clause (b) of Rule 12	
4	Member under clause (<i>c</i>) of Rule 12	Dr. Smt. Alka Rao
5	Member under clause (c) of Rule 12	Dr. Suraj Suchak
6	Member under clause (d) of Rule 12 Additional Chief Secretary/	Member
	Principal Secretary/ Secretary Public Health Department or his nominee.	
7	Member under clause (d) of Rule 12 Director of Health Service or	Member.
'	his nominee.	

(6) Hospital based Authorization Committee at P. D. Hinduja Hospital, Mahim (West), Mumbai consisting of following Members :---

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Sugandhi Iyer
2	Member under clause (b) of Rule 12	Dr. S. V. Prabhu
3	Member under clause (b) of Rule 12	Dr. C. V. Vanjani
4	Member under clause (c) of Rule 12	Dr. Mrs. Prarthana Utture
5	Member under clause (c) of Rule 12	Dr. Sudhir Patil
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

ş

Chairperson / Members Sr. No. Rule (3) (1) (2) Dr. Parag Rindani 1 Chairperson under clause (a) of Rule 12 Dr. Bchram Pardiwalla 2 Member under clause (b) of Rule 12 3 Member under clause (b) of Rule 12 Dr. Dipti Patel Dr. Smt. Sujatunnisa 4 Member under clause (c) of Rule 12 Attar. 5 Member under clause (c) of Rule 12 Dr. Salim Sachani Member under clause (d) of Rule 12 Additional Chief Secretary/ Member 6 Principal Secretary/ Secretary Public Health Department or his nominee. 7 Member under clause (d) of Rule 12 Director of Health Service or Member. his nominee.

(7) Hospital based Authorization Committee at Wockhardt Hospital, Mumbai Central, Mumbai consisting of following Members :—

(8) Hospital based Authorization Committee at Jupiter Hospital, Thane consisting of following Members :---

Sr. No		Chairperson / Members
(1)	(2)	(3)
1	Chairperson under clause (a) of Rule 12	Dr. Ravindra Karnjekar
2	Member under clause (b) of Rule 12	Dr. Pankaj Joshi
3	Member under clause (b) of Rule 12	Dr. Nikhil Kamat
4	Member under clause (c) of Rule 12	Dr.Smt. Manjushri Vivek Birla.
5	Member under clause (c) of Rule 12	Dr. Mahesh Bedekar
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(9) Hospital based Authorization Committee at Apollo Hospital, Navi Mumbai consisting of following Members :----

Sr. No (1)	o. Rule (2)		Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12		Dr. Narendra Trivedi
2	Member under clause (b) of Rule 12		Dr. Sobati Shyam
3	Member under clause (b) of Rule 12		Dr. Vishal Malhotra
4	Member under clause (c) of Rule 12	· · · · ·	Dr. Smt. Alka Patnaik
5	Member under clause (c) of Rule 12		Dr. Gangadhar Maheshwari.

ሄ

महाराष्ट्र शासन राजपत्र असाधारण भाग चार-अ, जून ३०, २०१८/आषाढ ९, शके १९४०

	महाराष्ट्र शासन राजपत्र असाधारण भाग चार-अ,	जून ३०, २०१८/आषाढ ९, शके	१९४० ५
Sr. No (1)	. Rule (2)		Chairperson / Members (3)
6	Member under clause (<i>d</i>) of Rule 12 Additional C Principal Secretary/ Secretary Public Health Dep nominee.		Member
7	Member under clause (<i>d</i>) of Rule 12 Director of I nominee.	Health Service or his	Member.
(1 Membe	0) Hospital based Authorization Committee at Ad ers :—	itya Birla Hospital, Pu	ine consisting of following
Sr. No (1)	. Rule (2)	₩0.30,300 ₩0.30,300	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12		Dr. Ashutosh Shrivastava
2	Member under clause (b) of Rule 12		Dr. Rahul Kallianpur
3	Member under clause (b) of Rule 12		Dr. Sandeep Bhavsar
4	Member under clause (c) of Rule 12		Dr. Smt. Pratibha Kane
5	Member under clause (c) of Rule 12		Dr. Raju Varyani
6	Member under clause (<i>d</i>) of Rule 12 Additional C Principal Secretary/ Secretary Public Health Dep nominee.	•	Member
7	Member under clause (<i>a</i>) of Rule 12 Director of his nominee.	Health Service or	Member.
,	11) Hospital based Authorization Committee at Dee wing Members :—	enanath Mangeshkar I	Hospital, Pune consisting
Sr. No			Chairperson / Members
(1)	(2)		(3)
1	Chairperson under clause (a) of Rule 12		Dr. Utkrant Kurlekar
2	Member under clause (b) of Rule 12		Dr. Asmita Bhave
3	Member under clause (b) of Rule 12		Dr. Jayant Agate
4	Member under clause (c) of Rule 12		Dr. Smt. Maya Tulpule
5	Member under clause (c) of Rule 12		Dr. Jayant Navarange
6	Member under clause (<i>d</i>) of Rule 12 Additional (Principal Secretary/ Secretary Public Health De		Member

Member. Member under clause (d) of Rule 12 Director of Health Service or 7 his nominee.

भागन्यार-अ-१३३-१अ,अ

his nominee.

51

महाराष्ट्र शासन राजपत्र असाधारण भाग चार-अ, जून ३०, २०१८/आषाढ ९, शके १९४०

(12) Hospital based Authorization Committee at Sahyadri Super Specialty Hospital, Pune consisting of following Members :---

Sr. No (1)	. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Deepa Divekar
2	Member under clause (b) of Rule 12	Dr. Jayshree Apte
3	Member under clause (b) of Rule 12	Dr. Dhananjay Chandkkar.
4	Member under clause (c) of Rule 12	Dr. Smt. Aarti Nimkar
5	Member under clause (c) of Rule 12	Dr. B. L. Deshmukh
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(13) Hospital based Authorization Committee at Ruby Hall Clinic, Pune consisting of following Members :---

Sr. No (1)	. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Sanjay Pathare
2	Member under clause (b) of Rule 12	Dr. N. C. Ydul
3	Member under clause (b) of Rule 12	Dr.C.P.Bajpai
4	Member under clause (c) of Rule 12	Dr. Smt. Padma Iyer
5	Member under clause (c) of Rule 12	Dr. Rajkumar Shah
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(14) Hospital based Authorization Committee at Jahangir Hospital, Pune consisting of following Members :---

Sr. No (1)). Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. N. G. Kamat
2	Member under clause (b) of Rule 12	Dr. Uma Divate
3	Member under clause (b) of Rule 12	Dr. Milind Botre
4	Member under clause (c) of Rule 12	Dr. Smt. Meenakshi Deshpande.
5	Member under clause (c) of Rule 12	Dr. Arun Haibe
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

52

Ę

(15) Hospital based Authorization Committee at Kamalnayan Bajaj Hospital, Aurangabad consisting of following Members :----

Sr. No (1)	. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Alok Shrivastav
2	Member under clause (b) of Rule 12	Dr. S. P. Ekbote
3	Member under clause (b) of Rule 12	Dr. R. B. Sharma
4	Member under clause (c) of Rule 12	Dr. Smt. Ujwala Dahipale.
5	Member under clause (c) of Rule 12	Dr. Santosh Ranjalkar
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee.	Member.

(16) Hospital based Authorization Committee at M. G. M. Hospital, Aurangabad consisting of following Members :---

Sr. No (1)	. Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (a) of Rule 12	Dr. Aparna Kakkad
2	Member under clause (b) of Rule 12	Dr. S. H. Talib
3	Member under clause (b) of Rule 12	Dr. S. A. Sami
4	Member under clause (c) of Rule 12	Dr. Smt. Rashmi Borikar.
5	Member under clause (c) of Rule 12	Dr. Yashwant Gade
6	Member under clause (<i>d</i>) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee	Member
7	Member under clause (<i>d</i>) of Rule 12 Director of Health Service or his nominee	Member.

Note.—Terms and conditions of Chairperson and Members of Hospital based Authorization Committees :—

(1) Each member of Authorization Committee shall have equal power.

(2) No official members of Authorization Committee shall be entitled to Travelling Allowance and Daily Allowance as admissible to Group A members of State Government.

(3) The Quorum of the Authorization Committee shall be minimum four and the quorum should not be complete without the participation of the Chairperson, the presence of Secretary (Health) or nominee and Director of Health Services or his nominee.

By order and in the name of the Governor of Maharashtra,

SURENDRA P. CHANKAR, Deputy Secretary to Government.

ON BEHALF OF GOVERNMENT PRINTING, STATIONERY AND PUBLICATION, PRINTED AND PUBLISHED BY IC DIRECTOR SHRI MANOHAR SHANKAR GAIKWAD, PRINTED AT GOVERNMENT CENTRAL PRESS, 21-A, NETAJI SUBHASH ROAD, CHARNI ROAD, MUMBAI 400 004 AND PUBLISHED AT DIRECTORATE OF GOVERNMENT PRINTING, STATIONERY AND PUBLICATIONS, 21-A, NETAJI SUBHASH ROAD, CHARNI ROAD, MUMBAI 400 004 EDITOR : IC DIRECTOR SHRI MANOHAR SHANKAR GAIKWAD.

List of IMA Members Hospital Based Authorization Committee with their Mobile Numbers

Sr. No.	Name of Hospital	Name of IMA Members with M	lobile Numbers
1.	Bombay Hospital,	1.Dr.Sunita Kshirsagar	9820118181
	Mumbai	2. Dr.Vijay Panjabi	9821061205
2.	Global Hospital, Parel	1. Dr.Smt. Kajal Ahuja	9833110302
	Mumbai	2. Dr. Pragji Vaja	9820482375
3.	Jaslok Hospital,	1. Dr. Smt Usha Shah	9322004145
	Mumbai	2. Dr. Anil Pachnekar	9869001873
4.	P.D.Hinduja Hospital,	1. Dr. Smt. Prarthana Utture	9833556069
	Mahim	2. Dr. Sudhir Patil	982030353
5.	Wockhardt Hospital,	1. Dr. Smt.Sujatunnisa Attar	7506033993
	Bombay Central	2. Dr. Salim Sachani	9892631484
6.	Kokilaben Ambani	1. Dr. Smt. Alka rao	9820338360
	Hospital, Andheri	2. Dr. Suraj Suchak	9920080151
7.	Fortis Hospital, Mulund	1. Dr. Smt.Sejal Sheth	9930951440
		2. Dr. Ramesh Punjani	9819327833
8.	Appolo Hospital Washi	1. Dr. Smt.Alka Patnaik	9323170532
		2. Dr. Gangadhar Maheshwari	9820011036
9.	Jupiter Thane	1. Dr.Smt.Manjushri Vivek Birla	9930140355
		2. Dr.Mahesh Bedekar	9821913638
10.	Aditya Birala	1. Dr.Smt.Pratibha Kane	9822090771
	Hospital, Pune	2. Dr.Raju Vayani	9822646025
11.	Deenanath	1. Dr.Smt.Maya Tulpule	9823709210
	Mangeshkar Hosp.	2. Dr.jayant Navrange	9561081674
12.	Sahaydri Super	1. Dr.Aarti Nimkar	9822304882
	specility Hosp,Pune	2. Dr.B.L.Deshmukh	9960172759
13.	Jahangi Hospital, Pune	1. Dr.Meenakshi Deshpande	9922464365
		2. Dr.Arun Halbe	9423586343
14.	Ruby Hall clinic	1. Dr.Padma Iyer	9373305154
		2. Dr.Rajkumar Shah	9422500666
15.	Kamalnayan Bajaj	1. Dr.Smt.Ujwala Dahiphale	
	Hosp,Aurangabad	2. Dr.Santosh Ranjalkar	
16.	M.G.M.Hosp,	1. Dr.Smt.Rashmi Borikar	
	Aurangabad	2. Dr.Yashwant Gade	

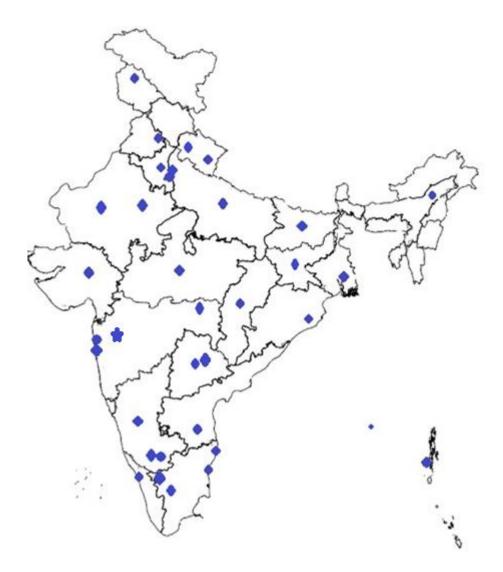
ICMR



भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंलालय, भारत सरकार

Indian Council of Medical Research Department of Health Research, Ministry of Health and Family Welfare, Government of India

INTER LABORATORY QUALITY CONTROL (ILQC) FOR MOLECULAR BASED TESTING LABORATORIES FOR COVID-19





Puducherry	Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
Rajasthan	Sawai Man Singh, Jaipur
	All India Institute of Medical Sciences, Jodhpur
Tamil NaduKing's Institute of Preventive Medicine &	
	Chennai
	Government Medical College, Theni
	Coimbatore Medical College, Coimbatore

List of Laboratories mapped with QC Labs

S.No	ALL INDIA INSTITUTE MEDICAL SCIENCES, BHOPAL
1.	Government Medical College, Shadol
2.	Bhopal Memorial Hospital and Research Centre, Bhopal
3.	Chhindwara Institute of Medical Sciences (CIMS), Chhindwara, Madhya Pradesh
4.	Amaltas Institute of Medical Science, Dewas
5.	Atal Bihari Vajpayee Government Medical College (ABVGMC), Vidisha, Madhya Pradesh
6.	Bundelkhand Medical College, Sagar
7.	Central Pathology Laboratory – Virology, People's Hospital, Bhopal
8.	CentraPath labs Private Ltd, Indore
9.	Chirayu Medical College & Hospital, Bhopal
10	Defence Research and Development Organisation, Gwalior
11	Gajara Raja Medical College, Gwalior
12	Gandhi Medical College, Bhopal
13	Government Medical College, Khandwa
14	Government Medical College, Ratlam, Madhya Pradesh
	ICAR-National Institute of High Security Animal Diseases (NIHSAD), Bhopal
16	Indian Institute of Science Education and Research (IISER), Bhopal
	L N Medical College and J K Hospital, Bhopal
18	Laboratory Medicine, Bansal Hospital, A Unit of Ayushman Medical Diagnostics Pvt Ltd,
10	Bhopal
	Mahatma Gandhi Memorial medical college, Indore
	National Institute of Research in Tribal Health (NIRTH), Jabalpur
	Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh
	R D Gardi Medical College (A Unit of Charitable Trust and Research Centre), Ujjain
	S.S. Medical College, Rewa
	Sampurna Sodani Diagnostic Clinic, Indore
	Sri Aurobindo Institute of Medical Sciences, Indore
26	Central Clinical Laboratory, RKDF Medical College Hospital and Research Center, Bhopal



4.	Pondicherry Institute of Medical Sciences, Pondicherry	
5.	Vector Control Research Centre, Pondicherry	
6.	Vinayaka Missions Medical College and Hospital, Karaikal	
7.	Central Laboratory, Sri Manakula Vinayagar Medical College & Hospital, Madagadipet,	
	Puducherry	

S.No	Kasturba Hospital for Infectious Diseases, Mumbai
1.	Department of Laboratory Medicine, Dr Balabhai Nanavati Hospital, Mumbai
2.	Department of Laboratory Medicine-P. D. Hinduja National Hospital & Medical Research Centre, Mumbai
3.	Dr Ajay Shah's Pathology Lab & Microbiology Reference Center, Mumbai
4.	Dr Jariwala Laboratory & Diagnostics LLP, Mumbai
5.	Dr Lal Path Labs, Dadar, Mumbai
6.	iGenetic Diagnostics Pvt. Ltd., Andheri East, Mumbai
7.	InfeXn Laboratories Pvt Ltd., Thane
8.	Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai
9.	Lifecare Diagnostic & Research Centre Pvt. Ltd., Mumbai
10.	Metropolis Healthcare Limites, Thane
11.	Metropolis Healthcare Ltd. Mumbai
12.	MGM Medical College and Hospital, Navi Mumbai, Maharashtra
13.	MGM New Bombay Hospital Vashi
14.	Molecular Laboratory, Jaslok Hospital & Research Center, Mumbai
15.	NM Medical, Mumbai
16.	Qualilife Diagnostics, Mumbai
17.	Sir H N Reliance Foundation Hospital and Research Centre Laboratory, Prathna Samaj, Mumbai
18.	SRCC Children's Hospital, Mumbai
19.	SRL Clinical Reference Lab, Goregaon Lab, Mumbai
20.	SRL Diagnostics- Dr Avinash Phadke (SRL Diagnostics Pvt Ltd), Mumbai
21.	Suburban Diagnostics(India) Pvt. Ltd., Mumbai
22.	Sunflower Laboratory And Diagnostic Center, Mumbai
23.	Thyrocare Technologies Ltd., Navi Mumbai
24.	Vaidya Lab Thane Unit of Millennium Special Lab Pvt Ltd., Thane
25.	Bai Jerbai Wadia Hospital for Children, Mumbai
26.	Seth G S Medical College and KEM Hospital, Mumbai
27.	GENEHEALTH DIAGNOSTICS PVT. LTD., MUMBAI

Adverse Drug Reactions Monitoring Centre (AMC)



To.

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI) MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA SECTOR-23, RAJ NAGAR, GHAZIABAD, U.P. 201 002.

> Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311 e-mail: <u>pypi@ipcindia.net</u>, <u>ipclab@vsnl.net</u>, Web: www.ipc.gov.in

File no.: IPC/NCC-PvPI/AMCs/2017-18/102

Date: 06/06/2017

Dr. Abhijeet Bhagat, Assistant Professor, Department of Pharmacology, Mahatma Gandhi Mission (MGM), N-6, Cidco, Aurangabad, Maharashtra-431003

Sub: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI.

Sir/Madam.

This is with reference to your letter of intent to participate in nationwide programme to monitor the safety of drugs, it is a matter of great pleasure to bring in your kind notice that the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) - Pharmacovigilance Programme of India (PvPI), Ghaziabad has agreed in principle to recognise your institution as an Adverse Drug Reactions Monitoring Centre under PvPI.

The detailed roles and responsibilities and resource materials will be sent to you after your

acceptance.

Please accept our heartiest congratulations.

With regards

Yours faithfully

(Dr. G. N. Singh) Secretary-cum-Scientific Director

Copy to:

a) The Dean, Mahatma Gandhi Mission (MGM), Aurangabad, Maharashtra

b) The Administrative Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh

c) The Finance & Accounts Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh

"Let us join hands with PvPI to ensure patients safety" ADR Reporting Help line (Toll Free): 1800-180-3024