

Major Achievements

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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: 07th Oct. 2019

Original Issue Date: 07th Oct. 2019

Issue No. 01 IAF Code: 37

**2019
Expiry Date: 07th Sep. 2020**

Recertification Date: 07th Sep. 2022*

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



Authorized By


Certification Manager

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.uqsr.org

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NAAC A Grade with CGPA 3.08

NAAC

Institutional Assessment and Accreditation

(Effective from July 2017)

Accreditation - (Cycle: 2)

**MGM INSTITUTE OF HEALTH SCIENCES, NAVI MUMBAI, Navi
Mumbai, Maharashtra, 410209**

Track ID : MHUNGN11010

AISHE-ID : U-0317

Visit dates : 19 - 10 - 2021 to 21 - 10 - 2021

Grade Sheet



NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL

An Autonomous Institution of the University Grants Commission

P.O. Box No. 1075, Nagarbhavi, Bengaluru - 560 072, INDIA

Name of the Institution: MGM INSTITUTE OF HEALTH SCIENCES, NAVI MUMBAI

Type of the Institution: Health Sciences University

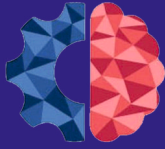
Dates of Visit: 19 - 10 - 2021 to 21 - 10 - 2021

| No | Criteria | Weightage (W _i) | Criterion-wise weighted Grade Point (CrWGP _i) | Criterion-wise Grade Point Averages (CrWGP _i / W _i) |
|--------------|---|-----------------------------|---|--|
| 1 | Curricular Aspects | 150 | 540 | 3.6 |
| 2 | Teaching-learning and Evaluation | 200 | 634 | 3.17 |
| 3 | Research, Innovations and Extension | 250 | 624 | 2.5 |
| 4 | Infrastructure and Learning Resources | 100 | 256 | 2.56 |
| 5 | Student Support and Progression | 100 | 371 | 3.71 |
| 6 | Governance, Leadership and Management | 100 | 321 | 3.21 |
| 7 | Institutional Values and Best Practices | 100 | 336 | 3.36 |
| Total | | $\sum_{i=1}^7 (W_i) = 1000$ | $\sum_{i=1}^7 (CrWGP_i) = 3082$ | 3.08 |

$$\text{Institutional CGPA} = \frac{\sum_{i=1}^7 (CrWGP_i)}{\sum_{i=1}^7 (W_i)} = \frac{3082}{1000} = 3.08$$

Grade: A

**Atal Ranking of Institutions on
Innovation Achievement
(ARIIA) 2021**



INNOVATION CELL
(Government of India)



Ministry of Education
(Government of India)



**ATAL RANKING OF INSTITUTIONS
ON INNOVATION ACHIEVEMENTS**

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.

Dr. Anil D Sahasrabudhe
Chairman, AICTE

Shri K Sanjay Murthy
Secretary (HE), MoE

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**



Ministry of
Education
Government of India



MoE's
INNOVATION CELL
(GOVERNMENT OF INDIA)



INSTITUTION'S
INNOVATION
COUNCIL
(Ministry of Education Initiative)



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.

Prof. Anil D. Sahasrabudhe
Chairman
AICTE

Dr. Abhay Jere
Chief Innovation Officer
MOE, Innovation Cell

Mr. Dipan Sahu
Assistant Innovation Director
MOE, Innovation Cell

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

Sector 1, 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.

Valid from : September 16, 2020
Valid thru : September 15, 2023



H-2020-0742

8 Certificate No.
H-2020-0742

Dr. Atul Mohan Kochhar
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



SI No. **001994**

001994



NABH and the NABH Accreditation Standards for Hospitals are ISQua Accredited

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



NABH and the NABH Accreditation Standards for Hospitals are ISQua Accredited

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)**



सूचना का
अधिकार
RIGHT TO
INFORMATION

दूरभाष/TEL : 26962819, 26567373
(EPABX) : 26565694, 26562133
: 26565687, 26562144
: 26562134, 26562122
फैक्स/FAX : 26960629, 26529745
Website : http://www.dsir.gov.in



सत्यमेव जयते

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
वैज्ञानिक और औद्योगिक अनुसंधान विभाग
टेक्नोलॉजी भवन, नया महरौली 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



F.No. 14/791/2019-TU-V

Date: 23rd April, 2020

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

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


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.

2. This is to inform you that it has been decided to accord recognition to **MGM Institute 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.

3. Receipt of this letter may kindly be acknowledged.

Yours faithfully,


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

NIRF
Overall (Rank-band 151-200)



National Institutional Ranking Framework
Ministry of Education
Government of India



- HOME
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India Rankings 2020: Overall (Rank-band: 151-200)

Institution list in alphabetical order

[Back](#)

| Name | City | State |
|--|--------------------|--------------------|
| Amity University | Gurugram, Haryana | Haryana |
| Amity University | Jaipur | Rajasthan |
| Annamalai University | Annamalainagar | Tamil Nadu |
| Anurag Group of Institutions | Hyderabad | Telangana |
| Avinashilingam Institute for Home Science & Higher Education for Women | Coimbatore | Tamil Nadu |
| Babashab Bhimrao Ambedkar University | Lucknow | Uttar Pradesh |
| Coimbatore Institute of Technology | Coimbatore | Tamil Nadu |
| Dharmsinh Desai University | Nadiad | Gujarat |
| English & Foreign Languages University | Hyderabad | Telangana |
| Government College of Technology | Coimbatore | Tamil Nadu |
| Indraprastha Institute of Information Technology Delhi | New Delhi | Delhi |
| Jawaharlal Nehru Technological University | Anantapur | Andhra Pradesh |
| Jaypee Institute of Information Technology | Noida | Uttar Pradesh |
| Jaypee University of Information Technology | Solan | Himachal Pradesh |
| JSS Science and Technology University | Mysuru | Karnataka |
| KLE Technological University | Dharwad | Karnataka |
| Konaseema Institute of Medical Sciences Research Foundation | Amalapuram | Andhra Pradesh |
| Kurukshetra University | Kurukshetra | Haryana |
| M. G. R. Educational and Research Institute | Chennai | Tamil Nadu |
| Maharaja Sayajirao University of Baroda | Vadodara | Gujarat |
| Manipur University | Imphal | Manipur |
| Mepco Schlenk Engineering College | Sivakasi | Tamil Nadu |
| MGM Institute of Health Sciences | Navi Mumbai | Maharashtra |
| N M A M Institute of Technology | Nitte, Udipi | Karnataka |
| Nagaland University | Zunheboto | Nagaland |
| National Institute of Technology Hamirpur | Hamirpur | Himachal Pradesh |
| National Institute of Technology Patna | Patna | Bihar |
| Nirma University | Ahmedabad | Gujarat |
| D E S College of Engineering | Mandya | 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 |
| Form of Organization: | 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.

Signature: *Keith Jansen*

Name: Keith Jansen

Title: SVP, International

Date: January 24, 2020

International Training Center

Signature: *Gurunath S Narshetty*

Name: GURUNATH S NARSHETTY

Title: DEAN

Date: 18-02-2020



Emergency Cardiovascular Care International Programs – 7272 Greenville Avenue, Dallas, Texas 75231-4596

Form Date: November 9, 2015

INCHARGE
MGM SKILLS LAB
DATE: 25/01/2020

DIRECTOR
MGM SKILLS LAB
DATE: 28/01/2020

Definitions:

(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

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, being placed in receivership or the filing by or against 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, agents, distributors, 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 any 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)

IN CHARGE
MGM SKILLS LAB
DATE: 28 / 01 / 2020



DIRECTOR
MGM SKILLS LAB
DATE: 28 / 01 / 2020

Institutional Animal Ethics Committee (IAEC)



भारत सरकार
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय

पशु कल्याण प्रभाग
पशुओं पर परीक्षण के नियंत्रण एवं पर्यवेक्षण के प्रयोजनार्थ समिति (सीपीसीएसईए)

Government of India
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

To

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

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 IAEC 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 Nominee |
| 7. | Dr. Vikas D. Dighe | Link Nominee |
| 8. | Dr. Dhanjit Kumar Das | Scientist from outside the Institute |
| 9. | Prof. Vishnu N. Thakare | Socially Aware Nominee |

Contd.,

[Handwritten Signature]

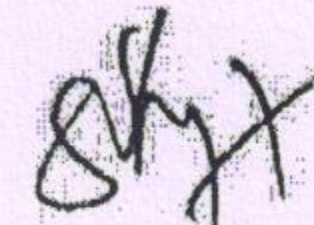
5वां तल, वायु ब्लॉक, इंदिरा पर्यावरण भवन, जोर बाग रोड नई दिल्ली-110003
दूरभाष : 011-24695231, टेलीफैक्स : 011-24695424, ईमेल : cpcsea-me1@gov.in, वेबसाइट : <http://cpcsea.nic.in>

5th Floor, Vayu Block, Indira Parayaran Bhawan, Jor Bagh Road, New Delhi-110003
Phone: 011-24695231, Telefax : 011-24695424, Email: cpcsea-me1@gov.in, Website: <http://cpcsea.nic.in>

3. 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 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,



(S. P. Singh)

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**



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

To

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, 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 in writing 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, 1940 and 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.

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 Sewaliker | B. COM (MSW-Master in Social Work) | Social Scientist |
| 12 | Mr. Mangesh V Shinde | B.Ed (M.Ed) | Lay Person |

(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

To

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 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 in writing 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, 1940 and 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.



सत्यमेव जयते

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 Prabhakar Rao 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.Phil, 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

To

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 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 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 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 (3) mentioned above.

S ESWARA
REDDY (S. Eswara Reddy)
Drugs Controller General (I) &
Licensing Authority

Digitally signed by S
ESWARA REDDY
Date: 2018.10.04 10:26:09





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

To

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.

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

| Sr. No. | Name of Member | Qualification | Role/Designation in Ethics Committee |
|---------|--------------------------------|---------------------------------------|--------------------------------------|
| 1 | Dr. Jaishree Ravindra Ghanekar | 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. Pramila Yadav | MBBS (MD-Pharmacology) | Chair Person ✓ |
| 6 | Dr. Pradeep R Jadhav | MBBS (MD-Pharmacology) | Member Secretary ✓ |
| 7 | Dr. Ipseeta S Ray | BSc (MSc.,PhD-Pharmacology) | Scientific Member |
| 8 | Dr. Ravindra Shrinivas 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 |

S ESWARA REDDY
Digitally signed by
S ESWARA REDDY
Date: 2018.10.04
10:05:30
Dr. S. Eswara Reddy
Drugs Controller General (I) &
Licensing Authority

**Zonal Transplantation Coordination Center,
Aurangabad**

No. 4401



नोंदणी प्रमाणपत्र

याद्वारे प्रमाणपत्र देण्यात येते की, खाली वर्णन केलेली सार्वजनिक विश्वस्तव्यवस्था ही आज, मुंबई सार्वजनिक विश्वस्तव्यवस्था अधिनियम, १९५० (सन १९५० चा मुंबई अधिनियम २९) या अन्वये Aurangabad Region, Aurangabad येथील सार्वजनिक विश्वस्तव्यवस्था नोंदणी कार्यालयात योग्य रितीने नोंदण्यात आलेली आहे.

सार्वजनिक विश्वस्तव्यवस्थेचे नाव : Zonal Transplantation Coordination Center, Aurangabad.

सार्वजनिक विश्वस्तव्यवस्थांच्या नोंदणी पुस्तकातील क्रमांक : E - 1298 (A. bad)
Dr. Sudhir Gajanan Kulkarni यांस प्रमाणपत्र दिले.

आज दिनांक 12.04.2016 २०१६

रोजी माझ्या सहीनिशी दिले.

शिवका



सही [Signature] 12/4/16
आयुक्त सहायक शासक
पदनाम, शासक विभाग, औरंगाबाद

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

वाचा :-

- १) 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

प्रस्तावना :-

वैद्यकीय शिक्षण व औषधी द्रव्ये विभागाच्या संदर्भाधिन क्र. १ येथील दिनांक ३०.०६.२०१८ च्या अधिसूचनेन्वये १६ रुग्णालयांमध्ये 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. | रुग्णालयाचे नाव | अपर मुख्य सचिव/ प्रधान सचिव/ सचिव (सा.आ.वि.) यांचे प्रतिनिधी | संचालक, आरोग्य सेवा यांचे प्रतिनिधी |
|--------|--|--|-------------------------------------|
| १ | बॉम्बे हॉस्पिटल, मुंबई | वैद्यकीय अधिक्षक, सामान्य रुग्णालय, मालवणी, मालाड, मुंबई | सहायक संचालक, ठाणे |
| २ | जसलोक हॉस्पिटल, मुंबई | | |
| ३ | पी.डी.हिंदुजा हॉस्पिटल, माहिम, मुंबई | | |
| ४ | व्होकार्ड हॉस्पिटल, मुंबई सेंट्रल, मुंबई | | |
| ५ | कोकीलाबेन धिरुभाई अंबानी | | |

| | | | |
|----|---|--|--|
| | हॉस्पिटल, अंधेरी, मुंबई | | |
| ६ | ग्लोबल हॉस्पिटल, परेल, मुंबई | वैद्यकीय | अतिरिक्त जिल्हा शल्य |
| ७ | फोर्टीस हॉस्पिटल, मुलुंड, मुंबई | अधिक्षक, मनोरुग्णालय, ठाणे | चिकीत्सक, जिल्हा |
| ८ | ज्युपिटर हॉस्पिटल, ठाणे | | रुग्णालय, ठाणे |
| ९ | अपोलो हॉस्पिटल, बेलापूर, नवी मुंबई | वैद्यकीय अधिक्षक, उपजिल्हा रुग्णालय, पनवेल | जिल्हा शल्य चिकीत्सक, जिल्हा रुग्णालय, ठाणे |
| १० | आदित्य बिल्हा हॉस्पिटल, चिंचवड, पुणे | सहायक संचालक, पुणे | जिल्हा शल्य चिकीत्सक, जिल्हा रुग्णालय, औंध, पुणे |
| ११ | दिनानाथ मंगेशकर हॉस्पिटल, एरंडवणे, पुणे | | |
| १२ | सहयाद्री हॉस्पिटल, एरंडवणे, पुणे | | |
| १३ | जहांगीर हॉस्पिटल, ससून रोड, पुणे | वैद्यकीय अधिक्षक, मनोरुग्णालय, पुणे | अतिरिक्त जिल्हा शल्य चिकीत्सक, जिल्हा रुग्णालय, पुणे |
| १४ | रुबी हॉल क्लिनिक, ससून रोड, पुणे | | |
| १५ | कमलनयन बजाज हॉस्पिटल, औरंगाबाद | सहायक संचालक, औरंगाबाद | जिल्हा शल्य चिकीत्सक, जिल्हा रुग्णालय, औरंगाबाद |
| १६ | एमजीएम हॉस्पिटल, औरंगाबाद | | |

२. सदर शासन निर्णय महाराष्ट्र शासनाच्या www.maharashtra.gov.in या संकेतस्थळावर उपलब्ध करण्यात आला असून त्याचा सांकेतांक 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,

- १) मा. राज्यपाल यांचे सचिव, राजभवन, मुंबई
- २) मा. मुख्यमंत्री यांचे प्रधान सचिव, मंत्रालय, मुंबई
- ३) 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

वर्ष ४, अंक ८०]

शनिवार, जून ३०, २०१८/आषाढ ९, शके १९४०

[पृष्ठे ७, किंमत : रुपये १५.००

असाधारण क्रमांक १३३

प्राधिकृत प्रकाशन

महाराष्ट्र शासनाने केंद्रीय अधिनियमान्वये तयार केलेले
(भाग एक, एक-अ आणि एक-ल यांमध्ये प्रसिद्ध केलेले नियम व आदेश यांब्यतिरिक्त) 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) | 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 |

(१)

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

(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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) of Rule 12 Director of Health Service or his nominee. | Member. |

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

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

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

| Sr. No. (1) | Rule (2) | Chairperson / Members (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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) 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) | 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. |

| Sr. No. (1) | Rule (2) | Chairperson / Members (3) |
|----------------|--|------------------------------|
| 6 | Member under clause (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) of Rule 12 Director of Health Service or his nominee. | Member. |

(10) Hospital based Authorization Committee at **Aditya Birla Hospital, Pune** consisting of following Members :—

| Sr. No. (1) | Rule (2) | 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) of Rule 12 Director of Health Service or his nominee. | Member. |

(11) Hospital based Authorization Committee at **Deenanath Mangeshkar Hospital, Pune** consisting of following Members :—

| Sr. No. (1) | Rule (2) | Chairperson / Members (3) |
|----------------|--|------------------------------|
| 1 | Chairperson under clause (a) of Rule 12 | Dr. Utkrant Kurlekar |
| 2 | Member under clause (b) of Rule 12 | Dr. Asmita Bhawe |
| 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) of Rule 12 Director of Health Service or his nominee. | Member. |

(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 Chandkar. |
| 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) of Rule 12 Director of Health Service or his nominee. | Member. |

(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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee. | Member |
| 7 | Member under clause (d) 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 (d) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee | Member |
| 7 | Member under clause (d) 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.

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

| Sr. No. | Name of Hospital | Name of IMA Members with Mobile Numbers |
|---------|--------------------------------------|--|
| 1. | Bombay Hospital, Mumbai | 1. Dr. Sunita Kshirsagar 9820118181 2. Dr. Vijay Panjabi 9821061205 |
| 2. | Global Hospital, Parel Mumbai | 1. Dr. Smt. Kajal Ahuja 9833110302 2. Dr. Pragji Vaja 9820482375 |
| 3. | Jaslok Hospital, Mumbai | 1. Dr. Smt. Usha Shah 9322004145 2. Dr. Anil Pachnekar 9869001873 |
| 4. | P.D. Hinduja Hospital, Mahim | 1. Dr. Smt. Prarthana Utture 9833556069 2. Dr. Sudhir Patil 982030353 |
| 5. | Wockhardt Hospital, Bombay Central | 1. Dr. Smt. Sujatunnisa Attar 7506033993 2. Dr. Salim Sachani 9892631484 |
| 6. | Kokilaben Ambani Hospital, Andheri | 1. Dr. Smt. Alka rao 9820338360 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 Hospital, Pune | 1. Dr. Smt. Pratibha Kane 9822090771 2. Dr. Raju Vayani 9822646025 |
| 11. | Deenanath Mangeshkar Hosp. | 1. Dr. Smt. Maya Tulpule 9823709210 2. Dr. Jayant Navrange 9561081674 |
| 12. | Sahaydri Super speciality Hosp, Pune | 1. Dr. Aarti Nimkar 9822304882 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 Hosp, Aurangabad | 1. Dr. Smt. Ujwala Dahiphale 2. Dr. Santosh Ranjalkar |
| 16. | M.G.M. Hosp, Aurangabad | 1. Dr. Smt. Rashmi Borikar 2. Dr. Yashwant Gade |

ICMR

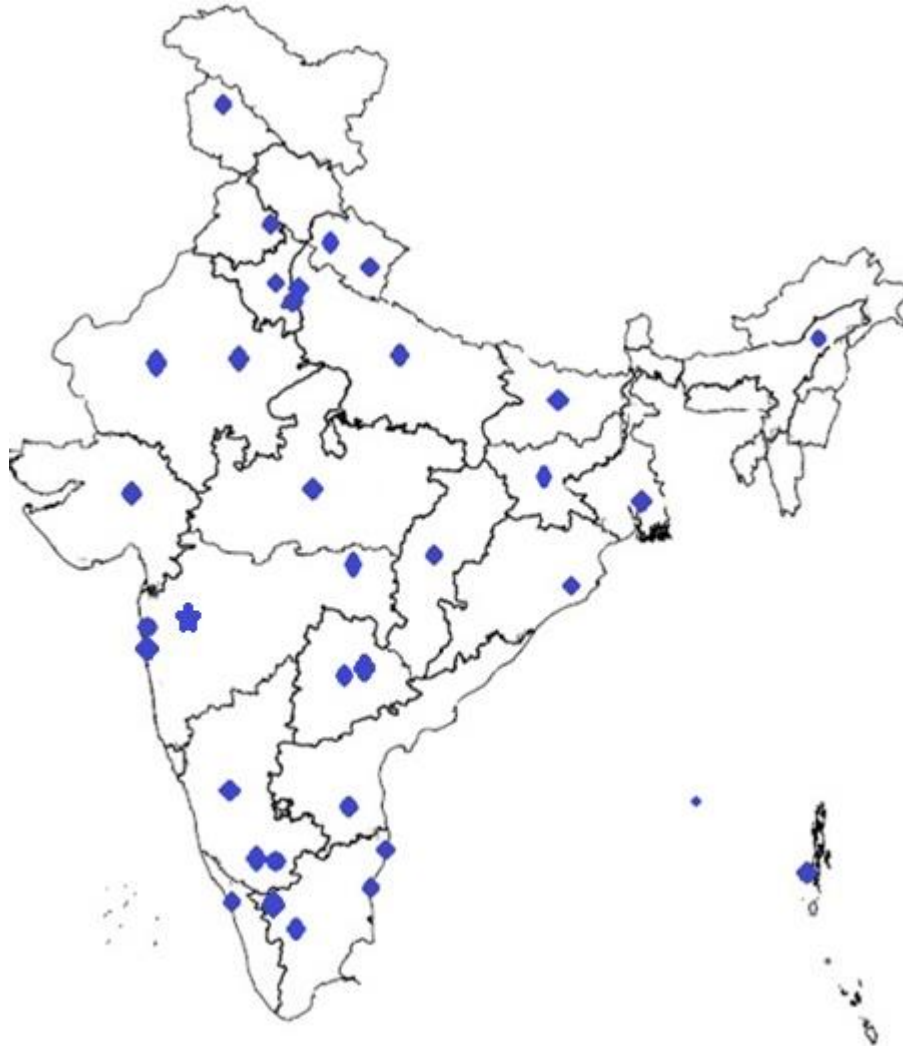


icmr
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कल्याण मंत्रालय, भारत सरकार

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 Nadu | King's Institute of Preventive Medicine & Research, 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 |
| 15 | ICAR-National Institute of High Security Animal Diseases (NIHSAD), Bhopal |
| 16 | Indian Institute of Science Education and Research (IISER), Bhopal |
| 17 | L N Medical College and J K Hospital, Bhopal |
| 18 | Laboratory Medicine, Bansal Hospital, A Unit of Ayushman Medical Diagnostics Pvt Ltd, Bhopal |
| 19 | Mahatma Gandhi Memorial medical college, Indore |
| 20 | National Institute of Research in Tribal Health (NIRTH), Jabalpur |
| 21 | Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh |
| 22 | R D Gardi Medical College (A Unit of Charitable Trust and Research Centre), Ujjain |
| 23 | S.S. Medical College, Rewa |
| 24 | Sampurna Sodani Diagnostic Clinic, Indore |
| 25 | 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 Limited, 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 |

| S.No | Kings George Medical University, Lucknow |
|------|--|
|------|--|

**Adverse Drug Reactions Monitoring Centre
(AMC)**



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: pvpi@ipcindia.net, ipcclab@vsnl.net, Web: www.ipc.gov.in

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

Date: 06/06/2017

To,

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:

- The Dean, Mahatma Gandhi Mission (MGM), Aurangabad, Maharashtra
- The Administrative Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh
- The Finance & Accounts Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh

"Let us join hands with PvPI to ensure patients safety"

ADR Reporting Helpline (Toll Free): 1800-180-3024