



CERTIFICATE



This is to certify that

PRAKASH INSTITUTE OF MEDICAL SCIENCES & RESEARCH

Urun-Islampur, Islampur- Sangali Road, Islampur Tal- Walwa Dist- Sangali-415409 Maharashtra INDIA

has implemented and maintains a Quality Management System.

Scope:

Provision of Medical education to students

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001: 2015

Certificate registration no.

50259183 QM15 2023-07-25

Date of certification

2023-07-25

Valid until

2026-07-24









DQS Inc.

Brad McGuire
Managing Director

Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA
Administrative Office: Deutsch Quality Systems (India) Pvt. Ltd., Ground Floor, South Wing, Vaishnavi Tech Park,
Sy.No.16/1 and 17/2, Bellandur Gate, Sarjapur Main Road, Ambalipura, Bengaluru - 560102 – India
The validity of this certificate, enrouly by verificably the QR-code.



NVIRONMENTAL SERVICES & CONSULTANCE



Is Issued to

PRAKASH INSTITUTE OF MEDICAL SCIENCES & RESEARCH URUN ISLAMPUR, 415409

For successful completion of Green Audit of the college for the academic year 2022-23 conducted by Elite Eco Solutions & Technology. This Green Audit included Water Audit, Energy Audit, Solid Waste Management Audit, Bio diversity Audit, Ambient Air Quality & Noise Monitoring, Carbon Footprint, Health & Well-being Audit, Green Campus Initiatives. The college is certified to have done exaptionally well to conserve environment & ensuring sustainable development.

Issued on 25th July 2023 Valid till July 2024







Er. Ankita A. Patil Director - Lead Auditor

Omkar Colony, Near Bus Stand, Islampur, Tal. Walwa, Dist. Sangli - 4154091 | Mob. - 9970303737 | Email- eliteecosolution@gmail.com







MAHARASHTRA MEDICAL COUNCIL, MUMBAI

CERTIFICATE OF ACCREDITATION

No. MMC/Accreditation/MED-0513/2024

Dated: 06/08/2024

This is to certify that, PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH, URUN-ISLAMPUR is hereby given full accreditation for conducting CPD Programmes / Workshops / Seminars / Short Courses / Conferences. This Certificate is valid upto 06/08/2029.



Registrar Maharashtra Medical Council

189-A, Anand Complex, 1st Floor, Sane Guruji Marg, Arthur Road Naka, Chinchpokali (W), Mumbai - 400 011. Website : www.maharashtramedicalcouncil.in







DIGITAL HEALTH FACILITY



PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH

Health Facility Registration No

IN2710014409

This is to certify that facility has been registered for Healthcare Facility Registry (HFR) under Ayushman Bharat Digital Mission, National Health Authority



National Health Authority Ministry of Health and Family Welfare Government of India

Date 2024-07-05







Government of India
Ministry of Education

Department of Higher Education

Statistics Division

New Delhi

Certificate



Reference No.C-57150-2019

This is to certify that Amit Balaso Patil of PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH has successfully uploaded the data of All India Survey on Higher Education(AISHE) 2019-2020.

(Madan Mohan) Deputy Director General

Name of the signatory

Dated: 26/11/2021





Government of India

Ministry of Education

Department of Higher Education

Statistics Division

New Delhi

Certificate



Reference No. C-57150-2020

This is to certify that Santosh Houserao Patil of PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH has successfully uploaded the data of All India Survey on Higher Education(AISHE) 2020-2021.

RRajesh

(Shri R. Rajesh)

Deputy Director General

Dated: 12/05/2022





Government of India Ministry of Education Department of Higher Education Statistics Division

New Delhi

Certificate



This is to certify that Mr. Himmat Shankar Japhale of PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH has successfully uploaded the data of All India Survey on Higher Education(AISHE) 2021-2022.

(Shri R. Rajesh)

Deputy Director General

Dated: 10/01/2023





Government of India
Ministry of Education
Department of Higher Education
Statistics Division

New Delhi

Certificate



Reference No. C-57150-2022

This is to certify that Santosh Houserao Patil of PRAKASH INSTITUTE OF MEDICAL SCIENCES AND RESEARCH has successfully uploaded the data of All India Survey on Higher Education(AISHE) 2022-2023.

PRajesh

(Shri R. Rajesh)

Deputy Director General

Dated: 08/02/2024



ECR/1601/Prakash/Inst/MH/2017/Re-Registration-2021

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



To

Dated: 2 9 APK

The Chairman/Member Secretary
Prakash Medical College IEC
Prakash Institute Of Medical Science and Research
Sangli Road Uran Islampur Walwa Sangli
Maharashtra - 415409, India

Maharashtra - 415409, India
Subject: Ethics Committee Registration No. ECR/1052/Inst/MH/2018/RR-21, amendment to the composition of the Ethics Committee-regarding.

Sir/Madam,

Please refer to your application for change in composition of the Re-Registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Registration number ECR/1052/Inst/MH/2018/RR-21 dated 30.06.2021 valid until 29.06.2026 is hereby amended as follows, with all conditions of the Registration Certificate initially granted to you, remaining the same including the condition that "the Ethics Committee shall review and accord approval to Clinical Trial and BA/BE Study protocol of new drugs and also conduct periodic review of the studies as per the New Drugs and Clinical Trial Rules, 2019".

	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Harish A. Nangare	BA, MS, PGDCR	Chairperson
2.	Dr. Basanagounda K. Patil	MBBS, MD (Community— Medicine)	Member Secretary
3.	Dr. Sachin B. Patil	MBBS, DCH, MD (Pharmacoloyg)	Medical Scientist
4.	Dr. Surpriya Patil	MBBS, MD, DGO (Ob. Gyn.)	Clinician
	- Maria	MBBS, MD (General Medicine)	Clinician
	Adv. Ravikant R. Patil	BA, LLB	Legal Expert
	Mrs. Raj R. Farnandes	MA	Social Scientist
		B.Com	Lay Person

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi) Central Lidensing Authority







File No. EC/21/000180

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: 30-Jun-2021

To

The Chairman Prakash Medical College IEC Prakash Institute Of Medical Science And Research Sangli Road Uran Islampur Walwa Sangli Maharashtra - 415409 India

Subject: Ethics Committee Re-Registration No. ECR/1052/Inst/MH/2018/RR-21 issued under New Drugs and

Sir/Madam.

Please refer to your application no. EC/RENEW/INST/2021/11878 dated 08-Jun-2021 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/1052/Inst/MH/2018/RR-21. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VENUGOPAL **GIRDHARILAL** SOMANI

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

Conditions of Registration

- 1. The registration is valid from 30-Jun-2021 to 29-Jun-2026, unless suspended or cancelled by the Central
- 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,
 - (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 nor 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 appointed by such institute or organization and one member who is affiliated with the contraction institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
- 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.
- 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 Compilee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or units bioequivalence study centre.

Medical

- 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/21/000180



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: 30-Jun-2021

Composition of the Ethics Committee:-

Sr.	Name of Member	Qualification	Role/Designation in Ethics Committee
No.		THE CARD Pharmacology)	Medical Scientist
1	Dr. Sachin Balasaheb Patil	MBBS (MD-Pharmacology)	1 D-110
2	Ms. Sanjivani R Patil	B. COM (Not Applicable)	Lay Person
		MBBS (Not Applicable)	Member Secretary
3	Dr. Pradeep Pilajirao Kulkarni	No. of the latest terms of	Chair Person
4	Dr. Harish Anand Rao Nangare	BAMS,PGDCR (Not Applicable)	Chair reison
5	13-11/01/12/11/01	MBBS (MD General Medicine)	Clinician
	Dr. Momin Mubin Rafia		Legal Expert
6	Mr. Ravikant R Patil	BA (LLB)	
		BA (MA)	Social Scientist
7	Ms. Raj R Fernandes		Clinician
8	Dr. Supriya V Patil	MBBS (MD OB.GYN)	Cirilotat

VENUGOPAL GIRDHARILAL SOMANI Criptoly, upwal by Vine and A. Debut and A.

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





NATIONAL PROGRAMME ON TECHNOLOGY ENHANCED LEARNING

To

2021-12-27

The Principal

PRAKASH INSTITUTE OF MEDICAL SCIENCES & RESEARCH, ISLAMPUR

PRAKASHNAGAR, ISLAMPUR SANGLI-ROAD, URUN-ISLAMPUR, TAL-WALWA, DIST SANGLI, MAH.

Dear Sir/Madam,

Sub: Establishing SWAYAM NPTEL Local Chapter in your college

Greetings from the NPTEL office.

This is to acknowledge the receipt of your letter accepting to host SWAYAM NPTEL Local Chapter

The Single Point of Contact (SPOC) nominated from your college is

Name of SPOC: ANITA T PATIL Designation: LIBRARIAN Department:LIBRARIAN Contact No(s):8007956537 E-mail id: anita86patil@gmail.com

We wish to inform you that all future correspondence related to NPTEL contents and online courses will be made to the afore-mentioned SPOC. He/she will be routinely updated with all the latest NPTEL initiatives which then may be circulated among the students.

We are also happy to share that a dedicated SWAYAM NPTEL Local Chapter web page is being created and your institution will have a separate page on it (http://archive.nptel.ac.in/LocalChapter

Thanking you.

Sincerely

Prof. R. K. Shevgaonkar

Principal Investigator

IIT BOMBAY

