



Shri Vithalrao Joshi Charities Trust's
B. K. L. WALAWALKAR HOSPITAL,
DIAGNOSTIC & RESEARCH CENTRE

ISO 9001: 2008 Certified
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Outward No:-BKLWH/IEC/04/2025

Date:- 09.01.2025

To
Dr. Gajana Velhal
Principial Investigator,
B.K.L.Walawalkar Hospital

Subject: Final Approval of Project # 305

The Institutional Ethics Committee reviewed your project to conduct the research study entitled "Rural Health Care Transformation Smart village Initiative – Addressing inequities and improving access to quality primary health care in rural India by harnessing integrated digital health solutions", discussed during the 91st meeting held on 05.01.2025 at 9.00 am in the Meeting Room in OPD building at B K L Walawalkar Rural Medical College and Hospital (BKLWRMC&H). Most members joined the meeting online.

The following members of the BKLWRMC&H-IEC joined the meeting:

Sr. No.	Name	Affiliation	Gender	Expertise
1	Dr. Mahendra Gulati	A201, Gold Coast Ivory Estate, Baner Road, Near Green Park Hotel Banner, Pune 8	Male	Chairman
2	Dr. Arvind Yadav	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Male	Member Secretary
3	Mr. Suresh S. Pakale	Advocate, Eliphistone Building, 1 st Floor, 10, Veer Nariman Road, Near Horniman Circle, Fort, Mumbai- 400001.	Male	Legal Expert
4	Mr. Mandar Phadke	17, Vrundavan Society, Navi Peth, Near Mhatre Bridge, Chintamani Bungalow, Pune- 30.	Male	Lay person
5	Dr. Veena Londhe	Athashri B 314, PAN Card Club Road, Baner, Pune- 411 045	Female	Lay person
6	Miss. Dipali Parab	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Social Scientist
7	Dr. Anand Joshi	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Male	Gastroenterology

8	Dr. Rita Mulherkar	B 813, Athashri, Pancard Club Road, Baner, Pune, 411045	Female	Scientist
9	Dr. Shripad Banvali	Professor & Consultant Haematologist- Oncologist, Tata Memorial Hospital, Mumbai. 11/A, Jyoti Sadan, Sitaladevi Temple Road, Mahim, Mumbai - 400016.	Male	Clinician
10	Dr. Shivaleela	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Clinical Pharmacologist
11	Dr. Suneeti Gore	1128 Shivajinagar, S.No. 504, 8, Kamala Regency, Dynaneshwar Paduka Chowk, Fergusson College road, Pune-411016	Female	Social Scientist
12	Dr. Sunita Patil	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Clinical Pharmacologist

The following documents were reviewed:

1. Project Submission Form
2. RAHAT ICMR Protocol Version 1.0 April 18, 2024
3. RAHAT Protocol Version 2 Date 24 August 2024 (Approved)
4. RAHAT Protocol for Data Privacy Version 1 date 3.12.2024
5. CCDC IEC Approval 5.05.2024
6. RAHAT Baseline Consent Form Institute Level version 1.0 dated 30.08.2024 , Focus Group Discussion in English & Hindi version 1.0 dated 30.08.2024 & Marathi version 1.0 dated 30.08.2024, In depth Interview- Facility level version 1.0 dated 30.08.2024, ANC Visit Observation – English version 1.0 dated 7.11.2024 Hindi version 1.0 dated 20.11.2024 & Marathi Version 1.0 dated 07.11.2024, Exit Interview version 1.0 dated 30.08.2024, Community Household Survey in English version 1.0 dated 22.10.2024 Hindi Version 1.0 dated 20.11.2024 & Marathi Version 1.0 dated 22.10.2024, Focus group discussion members of the community in English & Hindi version 1.0 dated 30.08.2024, In depth interview - members of the community version 1.0 dated 30.08.2024, Patient Consent form in Hindi version 1 dated 20.11.2024
7. RAHAT Baseline Information sheet & Approval Form- MRU/RD Situational Analysis in English version 1.0 dated 19 Sept 2024, For Facility Assessment in English version 1.0 dated 10 Sept 2024, Focus Group Discussion – Institute level English version 1.0 dated 30.08.2024
8. MOU of CCDC
9. CV & GCP Certificate

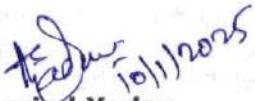
Decision: Approved. IEC approved the study till 09.01.2029 (5 Years). The Investigators are requested to submit Continuing Review report on or before 09.01.2026.

The study should be initiated only after-

- Registration of the study with Clinical Trials Registry India (CTRI)

Following points must be noted:

1. IEC has approved analysis of **334** subjects on this study. **(2000 from 6 study sites i.e. 334 from each site)**
2. IEC should be informed of the monthly progress of the study by the PI. Failure to submit the continuing review application/ annual status report may result in withdrawal of IEC approval.
3. IEC has approved the conduct of the study at **BKLWH**.
4. Principal Investigator and study team should be GCP trained.
5. PI and other investigators should notify initiation of the study.
6. The decision was arrived at through consensus/ unanimous or majority opinion amongst the voting members of IEC. Member(s) of the committee who is/ are listed as investigator(s) on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC. IEC members with any conflict of interest opted out from all deliberations on the proposal and did not participate in decision making.
7. Any change, modification or deviation in protocol must be informed to IEC. Any protocol modification or amendment must receive IEC approval.
8. This Ethics Committee is organized and operates according to Good Clinical Practice and Schedule Y requirements.
9. Any deviation/ violation/ waiver in the protocol must be informed to the IEC.
10. Principal Investigator should conduct the study accordance to the IEC approval protocol.
11. The PI should submit a report to the IEC at the time of Study Completion or Premature Termination/ Suspension/ Discontinuation Report as is applicable.
12. Principal Investigator should comply with regulations and guidelines as applicable.


Dr. Arvind Yadav,
Member Secretary,
IEC