

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

ISO 9001: 2008 Certified
Shreeksheeta Dervan, Taluka-Chiplun, Dist. Ratnagiri - 415606
Tel.: +91 02355 264137/264149 Fax: +91 02355 264181
Email: info@walawalkarhospital.com Website: www.walawalkarhospital.com

Outward No:-BKLWH/IEC/35/2024

Date:- 26.05.2024

**To,
Dr. Yogendra Shelke,
Principal Investigator,
BKLWH**

Subject: Final Approval of project # 267

The Institutional Ethics Committee reviewed your new application to conduct the research study entitled "**Assessing impact of IEC material on walk in individuals in ICTC & DSRC situated in Mumbai & Konkan region**", discussed during the **84th meeting held on 12.05.2024 at 9.00 am in the Meeting Room in OPD building at B. K. L. Walawalkar Hospital (BKLWH). Most members joined the meeting online.**

The following members of the BKLWH-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	Dr. Veena Londhe	Athashri B 314, PAN Card Club Road, Baner, Pune- 411 045	Female	Lay person
5	Miss. Dipali Parab	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Social Scientist
6	Dr. Anand Joshi	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Male	Gastroenterology
7	Dr. Rita Mulherkar	B 813, Athashri, Pancard Club Road, Baner, Pune, 411045	Female	Scientist
8	Dr. Shivaleela	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Clinical Pharmacologist
9	Dr. Suneeti Gore	1128 Shivajinagar, S.No. 504, 8, Kamala Regency, DynaneshwarPadukaChowk, Fergusson College road, pune- 411016	Female	Social Scientist
10	Dr. Sunita Patil	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Clinical Pharmacologist

The following documents were reviewed:

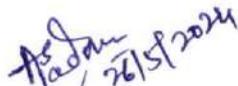
1. Project Submission Form
2. English & Marathi Consent Form

Decision: Approved. IEC approved the study till 11.10.2024 (4 months 15 days). The Investigators are requested to submit Continuing Review report on or before 30.10.2024.

Following points must be noted:

- 1. IEC has approved analysis of 245 subjects on this study.**
- 2. IEC should be informed of the yearly 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.

Thanking you,
Yours sincerely


Dr. Arvind Yadav,
Member Secretary,
IEC