



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/70/2024

Date:- 10.08.2024

To  
Dr. Suvarna Patil  
Principial Investigator,  
B.K.L.Walawalkar Hospital

**Subject: Final Approval of Project # 259**

The Institutional Ethics Committee reviewed your project to conduct the research study entitled "**Safe Motherhood and Healthy Rural Toddler (SMAHRT)**", discussed during the **86<sup>th</sup> meeting held on 13.07.2024 at 5.30 pm 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 <sup>st</sup> 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, Dynaneshwar Paduka Chowk, Fergusson College road, pune-411016	Female	Social Scientist

**The following documents were reviewed:**

1. Project Submission Form
2. English & Marathi Consent Form version 0.1 dated 16.01.2024 (Approved)
3. Case record form
4. Proposal
5. Reply to IEC
6. Covering letter
7. MOU

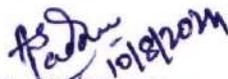
**Note: The IEC received query response letter dated 06.08.2024 reference along with the documents mentioned below which was reviewed by IEC.**

1. Reply to IEC query letter dated 06.08.2024

**Decision: Approved. IEC approved the study till 10.08.2027 (36 months). The Investigators are requested to submit Continuing Review report on or before 10.08.2025.**

Following points must be noted:

1. **IEC has approved analysis of 500 subjects on this study.**
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**