



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

ISO 9001: 2015 Certified

Kasarwadi, Post Sawarde, Taluka - Chiplun, Dist. Ratnagiri, Maharashtra - 415606.

Tel. : 02355 -264137 / 264149 / 9356427731 / 8847790149 / 9656510149

Email: info@walawalkarhospital.com Webiste:www.walawalkarhospital.com

Outward No:-BKLWH/IEC/58/2023

Date:- 18.07.2023

To,
Dr. Omkar Shahpurkar
Principal Investigator,
BKLWRMC

Subject: Final Approval on project # 212

Dear Dr. Shahpurkar

Institutional Ethics Committee reviewed and discussed your project entitled "A pilot study to evaluate the efficacy of saline extract of jackfruit seeds (JaSE) for the treatment of rhinitis and nasal congestion related ailments" discussed during the 73rd meeting held on 20.05.2023 at 6.00 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 IEC were present:

| 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, NaviPeth, Near Mhatre Bridge, Chintamani Bungalow, Pune-30. | Male | Lay person |
| 5 | Dr. Rita Mulherkar | B 813, Athashri, Pancard Club Road, Baner, Pune, 411045 | Female | Scientist |
| 6 | Miss. Dipali Parab | BKL Walawalkar Rural Medical College & Hospital, Sawarde | Female | Social Scientist |

| | | | | |
|----|------------------|--|--------|-------------------------|
| 7 | Dr. Shivaleela | BKL Walawalkar Rural Medical College & Hospital, Sawarde | Female | Clinical Pharmacologist |
| 8 | Dr. Sunita Patil | BKL Walawalkar Rural Medical College & Hospital, Sawarde | Female | Clinical Pharmacologist |
| 9 | Dr. Anand Joshi | BKL Walawalkar Rural Medical College & Hospital, Sawarde | Male | Gastroenterology |
| 10 | Dr. Suneeti Gore | Microbiologist, 1128 Shivajinagar, S.No. 504, 8, Kamala Regency, DynaneshwarPadukaChowk, Fergusson college road, pune-411016 | Female | Scientist |

The following documents were reviewed:

1. Project Submission Form
2. Study Protocol version 2 dated May 2023
3. Lay person's Summary
4. SOP for preparation of jackfruit seed extract (jase) in saline
5. ICF Consent form in English and Marathi version 1.0 dated 02 May 2023

Decision: Approved. IEC approved the study till 18.07.2025 (2 Years). The Investigators are requested to submit Continuing Review report on or before 18.07.2024

Following points must be noted:

1. **IEC has approved analysis of 60 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 BKLWRMC&H.**
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,

Arvind Yadav
22/3/2023

Dr. Arvind Yadav,
Member Secretary,
Institutional Ethics Committee