



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.

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Outward No:-BKLWH/IEC/75/2023

Date:- 12.09.2023

To,
Dr. Suvarna Patil,
Principal Investigator,
BKLWRMC & H

Subject: Final Approval of project # 243 (Protocol approved for conduct of clinical Trial)

The Institutional Ethics Committee reviewed your revised application to conduct the research study entitled "**Treatment Optimization for Blood pressure with Single-pil combinations in India**", discussed during the **76th meeting held on 03.09.2023 at 10.00 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	Mr. Mandar Phadke	17, Vrundavan Society, Navi Peth, 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

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7	Dr. Sunita Patil	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Female	Clinical Pharmacologist
8	Dr. Anand Joshi	BKL Walawalkar Rural Medical College & Hospital, Sawarde	Male	Gastroenterology
9	Dr. Suneeti Gore	Microbiologist, 1128 Shivaji Nagar, S.No. 504, 8, Kamala Regency, Dynaneshwar Paduka Chowk, Fergusson college road, pune-411016	Female	Scientist

The following documents were reviewed:

1. Project Submission Form
2. Study Protocol version 1.1 dated 19 April 2022 (Approved)
3. ICF Consent English, Hindi & Marathi version 2.0 dated 10 July 2023 (Approved)
4. CRF Version 1.0 dated 11 August (Approved)
5. Insurance Certificate
6. HMSC Approval
7. Trial Summary

The IEC received query response letter dated 09.09.2023 along with the documents mentioned below which was reviewed by IEC.

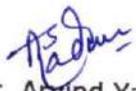
1. Reply to IEC query.

Decision: Approved. IEC approved the study till 12.09.2024 (1 years). The Investigators are requested to submit Continuing Review report on or before 12.09.2024.

Following points must be noted:

1. **IEC has approved analysis of 100 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.


Dr. Arvind Yadav,
 Member Secretary
 IEC

Dr. Arvind Yadav	Dr. Arvind Yadav	Dr. Arvind Yadav	Dr. Arvind Yadav
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The following documents were reviewed:
 1. Project Charter Form
 2. Study Protocol version 1.0 dated 15 April 2023 (Approved)
 3. ICF Consent Form (Adults) version 1.0 dated 10 July 2022 (Approved)
 4. GCP Version 1.0 dated 11 August 2022 (Approved)
 5. Insurance Certificate
 6. HMT Approval
 7. IEC Summary

The IEC has reviewed the documents mentioned above and has approved the study on 12.02.2024.

Investigator is requested to submit Continuing Review report on or before 12.02.2024.

- Following points must be noted:
- 1. IEC has approved analysis of 100 subjects on this study.
 - 2. IEC should be informed of the 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 BKLWICH&H.
 - 4. Principal Investigator and study team should be GCP aware.
 - 5. PI and other investigators should only conduct the study.
 - 6. The decision was taken at the 12th meeting. Members or majority opinion amongst the voting members of the committee (at the committee who is not listed as investigator) and research project listed but not all deliberations on the proposal and did not participate in the same meeting. Failure to not any of proposed study team or sponsor participation during the decision making of the IEC. IEC members who are not listed should not have any influence on the proposal and did not participate in decision making.
 - 7. Any change, modification, or suspension in protocol must be submitted to the IEC. Any change, modification, or suspension in protocol must be submitted to the IEC. Any change, modification, or suspension in protocol must be submitted to the IEC.
 - 8. This Ethical Committee document and minutes according to local law or practice and schedule 7 requirements.
 - 9. Any document, report or other information must be referred to the IEC.