



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

ISO 9001: 2008 Certified  
Shreekshetra 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/66/2024**

**Date:- 25.06.2024**

**To**

**Dr. Sunil Nadkarni**  
**Principal-Investigator,**  
**B.K.L.Walawalkar Hospital**

**Subject: Final Approval of Project # 200, approved for conduct of clinical Trial (Protocol No. SKLSPL/BKLWRH Cell Therapy Clinical Trial Protocol 001, Version No. 1.4, Dated 24.09.23)**

The Institutional Ethics Committee reviewed your revised application to conduct the research study entitled "**A Phase I clinical trial to examine the safety and efficacy of autologous, cultured disc chondrocytes embedded in PRF transplanted in patients' disc to maintain its function**", discussed during the **85<sup>th</sup> meeting held on 23.06.2024 at 9.00am in the Meeting Room in OPD building at BKLWalawalkar Rural Medical College and Hospital (BKLWRMC&H). Most members joined the meeting online.**

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

Dr. Rita Mulherkar declared conflict of interest and left the meeting while the proposal was being discussed.

| <b>Sr. No.</b> | <b>Name</b>          | <b>Affiliation</b>   | <b>Gender</b> | <b>Expertise</b>        |
|----------------|----------------------|--|---------------|-------------------------|
| 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              | Dr. Rita Mulherkar   | B 813, Athashri, Pancard Club Road, Baner, Pune, 411045  | Female        | Scientist               |
| 6              | Dr. Abhya Desai      | BKL Walawalkar Rural Medical College & Hospital, Sawarde   | Male          | Clinician               |
| 7              | Miss. Dipali Parab   | BKL Walawalkar Rural Medical College & Hospital, Sawarde   | Female        | Social Scientist        |
| 8              | Dr. Shivaleela       | BKL Walawalkar Rural Medical College & Hospital, Sawarde   | Female        | Clinical Pharmacologist |

|    |                     |   |        |                         |
|----|---------------------|---|--------|-------------------------|
| 9  | Dr. Sunita Patil    | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Female | Clinical Pharmacologist |
| 10 | Dr. Vijay D Dombale | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Male   | Clinician               |
| 11 | Dr. Anand Joshi     | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Male   | Gastroenterology        |
| 12 | Dr. Suneeti Gore    | Microbiologist, 1128 Shivaji Nagar, S.No. 504, 8, Kamala Regency, Fergusson college road, pune-411016 | Female | Scientist               |

As per Order dated 3<sup>rd</sup> March 2024, from Under Secretary, Govt. of India, two Stem Cell experts were co-opted for the meeting. The following Members attended the meeting:

1. Dr. Gaurav Narula, Tata Memorial Hospital, Mumbai, Male, Paediatric Oncologist
2. Dr. Sharmila Bapat, NCCS, Pune, Scientist

The following documents were reviewed:

| Sr. No. | Document  |
|---------|---|
| 1       | Project Submission Form   |
| 2       | Lay Person Summary version 1.1 dated 04.10.2022 (Approved)  |
| 3       | Consent form Research in English version 1.0 dated 17.01.2022 & Marathi version 1.0 dated 18.09.2022 (Approved)       |
| 4       | Consent form Clinical Trial in English version 1.0 dated 12.06.2022 & Marathi version 1.0 dated 12.06.2021 (Approved) |
| 5       | MOU SKLS  |
| 6       | CV PI & Co-PI   |
| 7       | Final Approval of CT dated 14.06.2024   |

**The following documents were reviewed at the 85<sup>th</sup> IEC meeting held on Sunday 23.06.2024**

|   |   |
|---|---|
| 1 | Clinical Trial Study Protocol - Protocol No. SKLSPL/BKLWRH Protocol 001, Version No. 1.4, dated 24.09.23 (Approved) |
| 2 | INVESTIGATOR'S BROCHURE Edition Number: 001 Date: 15-09-2023  |
| 3 | Form CT-06, No. CT- 0112024, date 14 June 2024  |
| 4 | CT-11 permission to Manufacture IND for clinical trial, date 14 June 2024   |

**Decision: Approved. IEC approved the clinical trial protocol No. SKLSPL/BKLWRH, Cell Therapy Clinical Trial Protocol 001, Version No. 1.4, dated 24.09.23, till 16.06.2027 (3 years). The Investigators are requested to submit Continuing Review report on or before 16.06.2025.**

**The study should be initiated only after-**

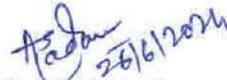
- Registration of the study with Clinical Trials Registry India (CTRI)

Following points must be noted:

1. IEC has approved analysis of 10 subjects on this study but, to submit the data of first 3 patients with 6 weeks follow up before proceeding for 4<sup>th</sup> patient and intimate to IEC and CDSCO for further review by the committee.
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. Mahendra Gulati**  
Chairperson,  
IEC



**Dr. Arvind Yadav,**  
Member Secretary,  
IEC